Chapter HSS 157

RADIATION PROTECTION

HSS 157.01 Public policy. (1) PURPOSE. Since ionizing radiations and their sources can be instrumental in the improvement of the health and welfare of the public if properly utilized, yet may be destructive or detrimental to life or health if carelessly or excessively employed or may detrimentally affect the environment of the state if improperly utilized, it is hereby declared to be the public policy of this state to encourage the constructive uses of radiation and to prohibit and prevent exposure to ionizing radiation in amounts which are or may be detrimental to health. The rules in this chapter, adopted in the interests of radiation safety, conform generally to nationally accepted standards.

(2) SCOPE. Except as otherwise specifically provided, this chapter, as authorized by ss. 254.33 to 254.45, Stats., known as the Radiation Protection Act, applies to all persons who receive, possess, use, transfer, own or acquire any source of radiation, provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. nuclear regulatory commission.

History: Cr. Register, September, 1982, No. 321, eff. 10−1−82**;** correction in (2) made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476.

HSS 157.02 Definitions. As used in this chapter:

(1) "Absorbed dose" means the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The units of absorbed dose are rads or Grays (Gy).

Concept	Special Unit*	SIUnit+	Metric Units
Absorbed Dose	1 rad	= 0.01Gy	= 0.01 J/kg
Dose Equivalent	1 rem	= 0.01Sv	= 0.01J/kg
Activity	1 curie	= 10^{10} Bq	= 3.7 × 10 disintegrations/sec
Exposure	1 roentgen	= −	= $2.58 \times 10_4$ J/kg

+ International metric system
* As used in this code chapter

(2) "Accelerator−produced material" means any material made radioactive by exposing it in a particle accelerator.

(3) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(4) "Act" means ss. 254.33 to 254.45, Stats.

(5) "Activity" means the number of atoms decaying per unit of time measured in curies or becquerels.

(6) "Added filter" means the filter added to the inherent filtration.

(7) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors, or gases.

(8) "Airborne radioactive area" means:

(a) Any room, enclosure, or operating area in which airborne radioactive material exists in concentrations in excess of the amounts specified in *Appendix D, Table 1, Column 1*; or

(b) Any room, enclosure, or operating area in which airborne radioactive material exists in concentrations which, averaged over the number of hours in any week during which individuals are in the area, exceed 25% of the amounts specified in *Appendix D, Table 1, Column 1*.

(9) "Aluminum equivalent" means the thickness of aluminum (type 1100 alloy) affording the same attenuation, under specified conditions, as the material in question.

Note: The nominal chemical composition of type 1100 aluminum alloy is 99.00% minimum aluminum, 0.12% copper.

(10) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x−ray system or subsystem.

(11) "Attenuation" means a decrease in exposure rate of radiation caused by passage through material.

(12) "Attenuation block" means a block or stack, having dimensions 20 cm by 20 cm by 3.8 cm, of type 1100 aluminum alloy or other materials having equivalent attenuation.

(13) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected locations(s) a required quantity of radiation.

(14) "Barrier" means a structure that prohibits the passage of radiation. (See "primary protective barrier" and "secondary protective barrier".)

(15) "Beam" means a collection of nearly parallel rays or particles.

(16) "Beam axis" means a line from the source through the centers of the x−ray fields.

(17) "Beam−limiting device" means a device which provides a means to restrict the dimensions of the x−ray field.

(18) "Becquerel (Bq)" means the unit of activity. One becquerel equals one disintegration per second: 1 Bq = 2.7 × 10^{-11} Ci = 1 d/s.

(19) "Byproduct material" means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material.

(20) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calen-

dar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No registrant shall change the method observed of determining calendar quarters for purposes of these rules except at the beginning of a calendar year.

(21) "Certified components" means components of x–ray systems which are subject to regulations promulgated under the U.S. Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968, Public Law 90–602, 42 USC 263b et. seq.

(22) "Certified system" means any x–ray system for use on human beings which has one or more certified components.

(23) "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.

(24) "Coefficient of variation (C)" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\overline{X}} = \frac{1}{\overline{X}}\left[\sum_{i=1}^{n} \frac{\left(\overline{X}_i - \overline{X}\right)^2}{n-1}\right]^{\frac{1}{2}}$$

where

s = Estimated standard deviation of the population.

$\overline{X}$ = Mean value of observations in sample.

Xi = ith observation in sample.

n = Number of observations in sample.

(25) "Collimator" means a beam limiting device.

(26) "Concrete equivalent" means the thickness of concrete based on a density of 2.35 grams per cubic centimeter (147 pounds per cubic foot) affording the same attenuation, under specified conditions, as the material in question.

(27) "Constant potential (cp)" means in radiological practice, a unidirectional potential (or voltage) which has little, or no, periodic variation. The periodic component is called the ripple potential or ripple voltage.

(28) "Contaminant" means any physical, chemical, biological, or radiological substance in water.

(29) "Controlled area" means a defined area in which the occupational exposure of personnel to radiation or to radioactive material is under the supervision of an individual in charge of radiation protection, and there is control of access, occupancy, and working conditions for radiation protection purposes.

(30) "Control panel" means that part of the x–ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

(31) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

(32) "Curie (Ci)" means a unit of activity defined as the activity of a quantity of any radioactive nuclide in which the number of disintegrations per second is 3.700×10^{10} Bq.

(a) "Millicurie (mCi) " means 1/1000 of a curie.

(b) "Microcurie (uCi)" means 1/1,000,000 of a curie.

(c) "Picocurie (pCi)" means 1/1,000,000,000,000 of a curie.

(33) "Deadman switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

(34) "Density (D)" means, as used in conjunction with image receptors, the logarithm to the base 10 of the ratio of the incident to the transmitted luminous flux:

$$D = \log_{10} \frac{\ell \text{ incident}}{\ell \text{ transmitted}}$$

(35) "Department" means the department of health and social services.

(36) "Diagnostic source assembly" means the tube housing assembly with a beam–limiting device attached.

(37) "Diagnostic–type protective tube housing" means a shockproof x–ray tube housing so constructed that the leakage radiation at a distance of 1 meter from the target cannot exceed 100 milliroentgens in 1 hour when the tube is operated at any of its leakage technique factors.

(38) "Diagnostic x–ray system" means an x–ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

(39) "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam. (See "scattered radiation".)

(40) "Dose distribution factor (DF)" means the factor used to express the modification of biological effect due to nonuniform distribution of internally deposited radionuclides.

(41) "Dose equivalent" means the product of the absorbed dose from ionizing radiation and such factors as account for differences in biological effectiveness due to the type of radiation and its distribution in the body. The "dose equivalent", usually referred to as "dose", has units of rem or Sievert (Sv).

Note: The term RBE dose has been used in the past, in both radiobiology and radiation protection. This term is now reserved for radiobiology only and is replaced by dose equivalent (DE) for radiation protection.

(42) "Dose rate" means the amount of dose equivalent per unit time.

(43) "Entrance exposure rate" means the roentgens per unit time at the point where the center of the useful beam enters the patient.

(44) "Equipment" means x–ray equipment.

(45) "Exposure" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. (The special unit of exposure is the roentgen.) Exposure also means one or more irradiations of a person for a healing arts purpose.

(46) "Exposure rate" means the exposure per unit of time.

(47) "Field" means that area of the intersection of the useful x–ray beam and any one of the set of planes parallel to and including the plane of the image receptor. (See "x–ray field.")

(48) "Field emission equipment" means the x–ray equipment which uses an x–ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(49) "Film badge" means a pack of appropriate photographic film and filters used to determine radiation exposure.

(50) "Filter" means material placed in the useful beam to absorb selected radiation energies.

(51) "Fluoroscopic imaging assembly" means a component which comprises a reception system in which x–ray photons produce a fluoroscopic image. It includes equipment housings, electrical interlocks, if any, the primary protective barrier and structural material providing linkage between the image receptor and the diagnostic source assembly.

(52) "FSD" means the distance from the focal spot to the skin surface of a patient.

(53) "General purpose radiographic x–ray system" means any radiographic x–ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

(54) "Gonadal shield" means a protective barrier for the testes or ovaries.

(55) "Gray (Gy)" means the special name for the unit of absorbed dose. 1 Gy = 1 J/kg = 100 rad.

(56) "Gross alpha particle activity" means the total radioactivity due to alpha particle emission as inferred from measurements on a dry sample.

(57) "Gross beta particle activity" means the total radioactivity due to beta particle emission as inferred from measurements on a dry sample.

(58) "Half–value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one–half of its original value. The contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(59) "High radiation area" means any area accessible to individuals in which there exists radiation at such levels that a major portion of the body could receive in any hour a dose in excess of 100 millirem.

(60) "Human use" means the internal or external administration of radiation or radioactive material to human beings.

(61) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x–ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

(62) "Individual" means any human being.

(63) "Inherent filtration" means the filtration permanently in the useful beam. It includes the window of the x–ray tube and any permanent tube or source enclosure.

(64) "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, orders, requirements and conditions of the department.

(65) "Interlock" means a device for precluding access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

(66) "Kilovolts constant potential (kvcp)" means the potential in kilovolts of a constant potential generator.

(67) "Kilovolts peak (kVp)" means the maximum x–ray potential, (See "peak tube potential".)

(68) "kWs" means the abbreviation for kilowatt second, which is equal to the product of peak kilovolts, amperes, and seconds.

(69) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(70) "Leakage radiation" means the radiation emanating from the diagnostic or therapeutic source assembly except for:

(a) The useful beam; and

(b) Radiation produced when the exposure switch or timer is *not* activated.

(71) "Leakage radiation" is the radiation which escapes through the protective shielding of an x–ray tube housing or radioisotope storage container.

(72) "Leakage technique factors" means the technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are as follows:

(a) For capacitor energy storage equipment, the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mAs) or the minimum obtainable from the unit, whichever is larger.

(b) For field emission equipment rated for pulsed operation, the maximum rated number of x–ray pulses in an hour for operation at the maximum rated peak tube potential.

(c) For all other equipment, the maximum rated continuous tube current for the maximum rated peak tube potential.

(73) "Light field" means the area of the intersection of the light beam from the beam–limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one–fourth of the maximum in the intersection.

(74) "Line pair" means an object in which parallel wires or strips are placed so that the space between each wire or strip is equal to the width of the wire or strip. A line pair is one space and a strip or wire.

(75) "Line voltage regulation" means the difference between the no–load and the load line potentials expressed as a percent of the load line potentials; that is,

$$\text{Percent line–voltage regulation} = 100(V_n - V_1)/V_1$$

where

V_n = No–load line potential

V_1 = Load line potential

(76) "Man–made beta particle and photon emitters" means all radionuclides emitting beta particles and/or photons listed in Maximum Permissible Body Burdens and Maximum Permissible Concentration of Radionuclides in Air or Water for Occupational Exposure, National Bureau of Standards Handbook 69 (See Appendix G), except the daughter products of thorium–232, uranium–235 and uranium–238.

(77) "Maximum contaminant level" means the maximum permissible level of a contaminant in water which is delivered to the consumer service outlet of the ultimate user of a public water system, except in the case of turbidity where the maximum permissible level is measured at the point of entry to the distribution system. Contaminants added to the water under circumstances controlled by the user, except those resulting from corrosion of piping and plumbing caused by water quality, are excluded from this definition.

(78) "Maximum line current" means the root mean square of the electrical current in the supply line of an x–ray machine operating at its maximum rating.

(79) "Maximum permissible dose (MPD)" means the maximum dose that the body of a person or specific parts thereof shall be permitted to receive in a stated period of time.

(80) "Millirad (mrad)" means one–thousandth of a rad.

(81) "Millirem (mrem)" means one–thousandth of a rem.

(82) "Milliroentgen (mr)" means one–thousandth of a roentgen.

(83) "Mobile equipment" means x–ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled. (See "x–ray equipment".)

(84) "Monitoring" means periodic or continuous determination of the exposure rate in an area (area mounting) or the exposure received by a person (personnel monitoring).

(85) "Natural radioactivity" means the radioactivity of naturally occurring nuclides.

(86) "Nuclear facility" means any reactor plant, or any equipment or device used for the separation of the isotopes of uranium or plutonium, the processing or utilizing of radioactive material or handling, processing or packaging of waste; any premise, structure, excavation or place of storage or disposition of waste or by–product; or any equipment used for or in connection with the transportation of such material.

(87) "Occupational dose" means exposure of an individual to radiation in the course of employment in which the individual's

duties involve exposure to radiation, except that "occupational dose" does not include any exposure of an individual to radiation for the purpose of diagnosis or therapy of such individual.

(88) "Occupancy factor (T)" means the factor by which the workload should be multiplied to correct for the degree or type of occupancy of the area in question. (See Appendix A, Table 4.)

(89) "Occupied area" means an area that may be occupied by persons or radiation–sensitive materials.

(90) "Operator" means a person who operates x–ray equipment or equipment containing radionuclides or handles sources of radionuclides.

(91) "Particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV.

(92) "Peak tube potential" means the maximum value of the potential difference across the x–ray tube during an exposure.

(93) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, or federal agency and any legal successor, representative, agent or agency of the foregoing.

(94) "Person in control" means the person directly responsible for the radiation installation.

(95) "Personnel monitoring equipment" means any device designed to be worn or carried by an individual for the purpose of measuring the radiation dose received including, but not limited to, film badges, pocket chambers, pocket dosimeters and film rings.

(96) "Position–indicating device (PID)" means a device on dental x–ray equipment used to indicate the beam position and to establish a definite source–surface (skin) distance. It may or may not incorporate or serve as a beam–limiting device.

(97) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure. (See "protective barrier".)

(98) "Protective apron" means an apron made of radiation–absorbing materials, used to reduce radiation exposure.

(99) "Protective barrier" means a barrier of radiation–absorbing material used to reduce radiation exposure.

(100) "Protective glove" means a glove made of radiation–absorbing materials used to reduce radiation exposure.

(101) "Public water system" means a system for the provision to the public of piped water for human consumption, if such system has at least 15 service connections or regularly serves an average of at least 25 individuals at least 60 days out of the year. Such system includes:

(a) Any collection, treatment, storage and distribution facilities under control of the operator of such system and used primarily in connection with such system, and

(b) Any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system. A public water system is either a "community water system" or a "non–community water system." "Community water system" means a public water system which serves at least 15 service connections used by year–round residents or regularly serves at least 25 year–round residents.

(102) "Qualified expert" means, with reference to radiation protection, a person having the knowledge and training to advise regarding radiation protection needs, to measure ionizing radiation, and to evaluate safety techniques as for example, persons having relevant certification from the American board of radiology or American board of health physics, or those having equivalent qualifications. With reference to shielding design, "qualified expert" means a person having particular knowledge and training in the field of medical x–ray and gamma–ray shielding.

(103) "Quality factor (QF)" means the linear–energy–transfer–dependent factor by which absorbed doses are to be multiplied to obtain, for radiation protection purposes, a quantity that expresses on a common scale for all ionizing radiations the irradiation incurred by exposed persons. The QF for x–rays, gamma–rays, and the beta–rays is 1. The QF for alpha–rays is 20, for neutrons it is 10.

(104) "Rad" means the unit of absorbed dose. One rad is 100 ergs per gram is 0.01 Gray.

(105) "Radiation" means electromagnetic radiations such as x–rays and gamma rays, or particular radiations such as electrons or beta particles, protons, neutrons, or alpha particles, usually of high energy, but in any case it includes all radiations capable of producing ions directly or indirectly in their passage through matter.

(106) "Radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of 5 millirem, or in any 5 consecutive days a dose in excess of 100 millirem. (Also see "high radiation area".)

(107) "Radiation hazard" means a condition under which persons might receive radiation in excess of the maximum permissible dose, or radiation damage might be caused to materials.

(108) "Radiation installation" means any location or facility where radiation machines are used or where radioactive material is produced, transported, stored, disposed of or used for any purpose.

(109) "Radiation machine" means any device that produces radiation when in use.

(110) "Radiation safety officer" means a person who has the knowledge and responsibility to apply appropriate radiation protection rules.

(111) "Radiation source" means a radiation machine or radioactive material as defined herein.

(112) "Radioactive material" means any solid, liquid or gaseous substance which emits radiation spontaneously.

(113) "Radioactivity" means the disintegration of unstable atomic nuclei by the emission of radiation.

(114) "Radiograph" means an image receptor on which the image is created directly or indirectly by an x–ray pattern and results in a permanent record.

(115) "Radiographic imaging system" means any system whereby a permanent or semipermanent image is recorded on an image receptor by the action of ionizing radiation.

(116) "Rating" means the maximum operating limits of the machine or component as specified by the manufacturer.

(117) "Recording" means producing a film, videotape, or other permanent form of an image resulting from x–ray photons.

(118) "Registration" means registration with the department in accordance with this chapter.

(119) "Regulations of the U.S. department of transportation" means the regulations in 49 CFR 170–189, 14 CFR 103, and 46 CFR 146.

(120) "Rem" means the unit of dose equivalent from ionizing radiation to the total body or any internal organ or organ system. A millirem (mrem) is 1/1000 of a rem. For diagnostic x–rays one rem is equivalent to one rad. The rem is a measure of the dose of any ionizing radiation to body tissues in terms of its estimated biological effect relative to a dose of one roentgen (R) of x–rays.

Note: The relation of the rem to other dose units depends upon the biological effect under consideration and upon the conditions of irradiation. Any of the following is considered to be equivalent to a dose of one rem:

(a) A dose of 1 R due to X– or gamma radiation;

(b) A dose of 1 rad due to X–, gamma, or beta radiation;

(c) A dose of 0.1 rad due to neutrons or high energy protons ;

(d) A dose of 0.05 rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye; if it is more convenient to measure the neutron

flux, or equivalent, than to determine the neutron dose in rads, as provided in (c) above, one rem of neutron radiation may be assumed to be equivalent to 14 million neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one rem may be estimated from the following table:

Table 157–A

NEUTRON FLUX DOSE EQUIVALENTS

Neutron energy (MeV)	Number of neutrons per square centimeter equivalent to a dose of 1 rem (neutrons/cm^2)	Average flux to deliver 100 millirem in 40 hours (neutrons/cm^2 per second)
Thermal	970×10^6	670
0.0001	720×10^6	500
0.005	820×10^6	570
0.02	400×10^6	280
0.1	120×10^6	80
0.5	43×10^6	30
1.0	26×10^6	18
2.5	29×10^6	20
5.0	26×10^6	18
7.5	24×10^6	17
10.0	24×10^6	17
10 to 30	14×10^6	10

(121) "Repair person" or "service person" means any individual who maintains an x–ray system. It is not limited to a manufacturer, assembler or user.

(122) "Research and development" means:

(a) Theoretical analysis, exploration, or experimentation; or

(b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

(123) "Response time" means the time required for an instrument system to reach 90% of its final reading when the radiation–sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

(124) "Restricted area" means any area to which access is controlled by the licensee or registrant for the purpose of protecting individuals from exposure to radiation and radioactive material. "Restricted area" shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as such an area.

(125) "Roentgen (R)" means a unit of exposure to x–or gamma–radiation. One roentgen is an exposure to x–radiation or gamma–radiation such that the associated corpuscular emission per 0.001293 g of air produces, in air, ions carrying one esu of quantity of electricity of either sign.

(126) "Scattered radiation" means the radiation that, during passage through matter, has been deviated in direction. (See "direct scattered radiation".)

(127) "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

(128) "Secondary protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposures. (See "protective barrier".)

(129) "Secondary radiation" means a form of scattered radiation emitted by any irradiated material. (See "radiation".)

(130) "Shutter" means a movable and controllable device, generally of lead, fixed to a radiation source, employed to intercept and collimate the useful beam.

(131) "Sievert (Sv)" means the special name for the unit of dose equivalent. One Sv = 1 J/kg = 100 rem.

(132) "Source" means the focal spot of the x–ray tube.

(133) "Source–image receptor distance" or "SID" means the distance from the source to the center of the input surface of the image receptor.

(134) "Source material" means uranium or thorium, or any combination thereof, in any physical or chemical form, or ores which contain by weight one–twentieth of one percent (0.05%) or more of uranium, thorium, or any combination thereof. Source material does not include special nuclear material.

(135) "Source of radiation" means any radioactive material, or any device or equipment emitting or capable of producing radiation.

(136) "Special form" means any of the following physical forms of licensed material of any transport group (10 CFR 71.4 (0)):

(a) The material is in solid form having no dimension less than 0.5 millimeter or at least one dimension greater than 5 millimeters; does not melt, sublime, ignite in air at a temperature or 1,000ºF.; will not shatter or crumble if subjected to the percussion test described in paragraph (c); and is not dissolved or converted into dispersible form to the extent of more than 0.005% by weight by immersion for 1 week in water at 68°F. (20°C.) or in air at 86°F. (31°C.): or

(b) The material is securely contained in a capsule having no dimension less than 0.5 millimeter or at least one dimension greater than 5 millimeters, which will retain its contents if subjected to the tests prescribed in paragraph (c) and which is constructed of materials which do not melt, sublime, or ignite in air at 1,475°F. (802°C.), and do not dissolve or convert into dispersible form to the extent of more than 0.005% by weight by immersion for 1 week in water at 68°F. (20°C.) or in air at 86°F. (31°C.): or

(c) The following tests are for special form licensed material:

1. Free Drop – A free drop through a distance of 30 feet onto a flat essentially unyielding horizontal surface, striking the surface in such a position as to suffer maximum damage.

2. Percussion – Impact of the flat circular end of a 1 inch diameter steel rod weighing 3 pounds, dropped through a distance of 40 inches. The capsule or material shall be placed on a sheet of lead, of hardness number 3.5 to 4.5 on the Vickers scale, and not more than 1 inch thick, supported by a smooth essentially unyielding surface.

3. Heating – Heating in air to a temperature of 1,475°F. (802°C.) and remaining at that temperature for a period of 10 minutes.

4. Immersion – Immersion for 24 hours in water at room temperature. The water shall be at pH 6–pH 8, with a maximum conductivity of 10 micromhos per centimeter.

(137) "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U–235 in quantities not exceeding 350 grams of contained U–235; U–233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175 \text{ (grams contained U–235)}}{350} + \frac{50 \text{ (grams U–233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

(138) "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

(139) "Stationary equipment" means x–ray equipment which is installed in a fixed location. (See "x–ray equipment".)

(140) "Stray radiation" means the sum of leakage and scattered radiation.

(141) "Supplier of water" means any person who owns or operates a public water system.

(142) "Surface exposure integral" means the product of the exposure at the skin entrance and the beam area at the skin entrance for all non–dental projections. For dental projections, the surface exposure integral is computed as the exposure at the cone tip times the beam area at the cone tip. The units are roentgen square centimeter (Rcm).

(143) "Survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of sources of radiation under a specific set of conditions. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive material present.

(144) "Technique factors" means the conditions of operation. They are specified as follows:

(a) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(b) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x–ray pulses.

(c) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

(145) "Test" means a method for determining the characteristics or condition of sources of radiation or components thereof.

(146) "Therapeutic–type protective tube housing" means the tube housing with tube installed and it includes high voltage and/or filament transformers and other appropriate elements when they are contained within that housing.

(147) "Total filtration" means the sum of the inherent and added filtration.

(148) "Tube" means an x–ray tube, unless otherwise specified.

(149) "Tube housing assembly" means the tube housing with tube installed. It includes high–voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

(150) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(151) "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

(152) "Unrestricted area" means any area to which access is not controlled by the person in control for purposes of protection of individuals from exposure to radiation and radioactive material, and any area used for residential quarters.

(153) "Use factor (U)" means the fraction of the workload during which the useful beam is pointed in the direction under consideration. (See Appendix A, Table 3.)

(154) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam–limiting device when the exposure switch or timer is activated.

(155) "User" means a person, organization, or institution having administrative control over one or more installations or mobile sources of radiation.

(156) "Variable–aperture beam–limiting device" means a beam–limiting device which has capacity for step–less adjustment of the x–ray field size at a given SID.

(157) "Visible area" means that portion of the input surface of the image receptor over which incident x–ray photons produce a visible image.

(158) "Worker" means an individual engaged in work under a registration issued by the department and controlled by the person in control, but does not include the person in control.

(159) "Workload (W)" means a measure in suitable units of the amount of use of radiation equipment. The workload is expressed in milliampere–minutes per week for x–ray sources and roentgens per week at 100 centimeters from the source for gamma–ray sources.

(160) "X–ray control" means a device which controls input power to the x–ray high–voltage generator and the x–ray tube. It includes equipment which controls the technique factors of an x–ray exposure.

(161) "X–ray equipment" means an x–ray system, subsystem or a component thereof.

(a) "Mobile x–ray equipment" means mounted on a permanent base with wheels, casters, or wheels and casters for moving while completely assembled.

(b) "Portable x–ray equipment" means designed to be hand–carried.

(c) "Stationary x–ray equipment" means installed in a fixed location.

(d) "Transportable x–ray equipment" means installed in a vehicle or trailer.

(162) "X–ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one–fourth of the maximum in the intersection.

(163) "X–ray high–voltage generator" means a device which transforms electrical energy from the potential supplied by the x–ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x–ray tube(s), high–voltage switches, electrical protective devices and other appropriate elements.

(164) "X–ray subsystem" means any combination of two or more components of any x–ray system for which there are requirements specified in ss. HSS 157.05, 157.06, and 157.08.

(165) "X–ray system" means an assemblage of components for the controlled production of x–rays. It includes minimally an x–ray high–voltage generator, an x–ray control, a tube housing assembly, a beam–limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

(166) "X–ray tube" means an electron tube which is designed to convert electrical energy into x–ray energy.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82; correction in (4) made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476.

HSS 157.03 General requirements. This section establishes requirements for use of x–ray equipment. The provisions of this section are in addition to, and not in substitution for, other applicable provisions of this chapter.

(1) SPECIFIC DUTIES OF THE PERSON IN CONTROL. The person in control of a radiation installation or radiation source shall establish and maintain operational procedures so that the radiation exposure of each worker is kept as far below the maximum permissible exposure as is practicable. The person in control may designate another person to be responsible for directing the operation of the registered radiation installation. The person in control shall assure that the following provisions are met in the operation of the x–ray machine(s):

(a) An x–ray machine which does not meet the provisions of this chapter may not be operated for diagnostic or therapeutic purposes if so directed by the department in writing. Written notifica-

tion of the correction of all x–ray machine noncompliance items shall be furnished to the department within 30 days following receipt of the survey report.

(b) Individuals who will be operating the x–ray equipment shall be instructed in the safe operating procedures and be competent in the safe use of the equipment.

(c) A chart shall be provided in the vicinity of each x–ray system control panel. This chart shall specify for all routine exposures performed on that system the following minimum information:

1. Exam title;

2. Patient's anatomical size versus technique factors to be utilized;

3. Type of and size of the film or film–screen combination to be used;

4. Type of grid to be used, if any;

5. Source to image receptor distance to be used; and

6. Type and location of placement of gonadal shielding to be used.

(d) Written safety procedures and requirements shall be provided to each individual operating x–ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x–ray system. The operator should be able to demonstrate familiarity with these procedures and rules.

(e) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

1. All individuals shall be positioned such that no part of the body not protected by 0.5 mm lead equivalent will be struck by the useful beam;

2. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent;

3. Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor;

4. When a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation which could result in that individual receiving one–quarter of the maximum permissible dose as defined in s. HSS 157.12 (2), additional protective devices shall be used.

(f) Gonadal protection shall be provided between the source and the patient for all patients under the age of 50 during x–ray examinations as follows:

1. When the gonads will not be in the useful beam (e.g., by protective aprons, drapes or curtains);

2. When the gonads will be in a correctly collimated useful beam but not imaged on the image receptor for the radiographic examination, such as when the beam is circular (e.g., by protective aprons or film dividers of adequate size), or when the gonads will be in the useful beam and will be imaged on the image receptor (e.g., by gonadal (shield) diaphragms or cups of appropriate size);

3. Gonadal shields shall provide an attenuation of not less than 95% of the incident radiation. This criterion shall be judged to have been met if lead equivalent material of the following minimum thickness is used for the gonadal shield:

a. For < 101 kVp use 0.25 mm.

b. For 101 to < 151 use 0.5 mm.

c. For 151 to 300 kVp use 1.0 mm.

4. Exceptions to the provisions of subds. 1., 2. and 3. shall be allowed for those examinations or patient's physical condition which are noted either on the facility's radiation safety instructions required in par. (d) or on the technique chart in par. (c) 3.

5. Unnecessary fetal exposure is especially undesirable. Therefore, the operators and practitioners should make appropriate prior inquiries with respect to possible pregnancy.

(g) No person may be exposed to the useful beam except for healing arts purposes, each exposure of which has been authorized by a licensed practitioner of the healing arts. X–ray exposure is specifically prohibited for the following purposes:

1. Exposure of an individual for training, testing, demonstration, administration, employment, or other purposes unless there are health care requirements and proper prescription has been provided;

2. Exposure of an individual for the purpose of healing arts screening without prior written approval of the department. "Screening" means an exposure of a person without prior examination disclosing a need for x–ray study and prescription for such a study by a licensed practitioner.

(h) When a patient or film must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The safety rules required by this section shall list individual projections where holding devices cannot be utilized;

2. Written safety procedures as required by par. (d) shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder, preferably of post–reproductive age, shall be protected as required by s. HSS 157.12;

4. No person shall be used routinely to hold film or patients;

5. In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.25 mm lead equivalent material;

6. During therapy procedures the exposure of any human holder shall be monitored and recorded.

(i) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include but is not limited to:

1. The speed of the film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations;

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality;

3. Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation; and

4. Fluoroscopic imaging devices used for optical viewing which are not mechanically linked to the x–ray tube shall not be utilized.

(j) Each image (film, film set, etc.) shall be interpreted by a licensed practitioner, and a permanent record shall be made of the interpretation of the total examination.

(k) All persons who are associated with the operation of an x–ray system shall be subject to the occupational exposure limits and the requirements for the determination of the doses which are stated in s. HSS 157.12 (2). In addition, the following requirements are made:

1. When protective clothing or devices are worn on portions of the body and a monitoring device is required, at least one such device shall be utilized. When an apron is worn, the monitoring device shall be worn on the collar outside of the apron. The dose to the whole body based on the maximum dose attributed to any one critical organ (which are the gonads, the blood forming organs, or lens of the eye) shall be recorded in the reports required by s. HSS 157.12 (3) (a). If more than one device is used and a

record is made of the data, each dose shall be identified with the area where the device was worn on the body;

2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited; to determine the cause and to take steps to prevent its recurrence;

4. The department shall be notified of any excessive or abnormal exposure as follows:

a. The person in control or a substitute shall immediately notify the department by telephone or telegraph of any incident involving registered sources of ionizing radiation which may have caused or threatens to cause exposure of the whole body of any individual to 25 rem or more of radiation; exposure of the skin of the whole body of any individual to 150 rem or more of radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of radiation;

b. The person in control or a substitute shall within 24 hours notify the department by telephone or telegraph of any incident involving registered sources of ionizing radiation which may have caused or threatens to cause exposure of the whole body of any individual to 5 rem or more of radiation; exposure of the skin of the whole body of any individual to 30 rem or more of radiation; or exposure of the feet, ankles, hands or forearms to 75 rem or more of radiation;

c. The person in control or a substitute shall, within 30 days, notify the department in writing of the accumulative exposure of any employe when the exposure exceeds 1.25 rem per quarter.

(L) Periodic radiation surveys shall be conducted as indicated and records kept of such surveys, including descriptions of corrective measures.

(2) INFORMATION AND MAINTENANCE RECORD AND ASSOCIATED INFORMATION. The person in control shall maintain at least the following information for each x−ray machine:

(a) Maximum rated technique factors;

(b) Model numbers of all certifiable components;

(c) Aluminum equivalent filtration of the useful beam, including any routine variation;

(d) Tube rating charts and cooling curves;

(e) Records of surveys, calibrations, maintenance and modifications (from the original schematics and drawings) performed on the x−ray machine after the effective date of this chapter, along with the names of persons who performed the service;

(f) A scale drawing of the room in which a stationary x−ray system is located. The drawing shall denote the type of materials and their thickness (or lead equivalence) provided by each barrier of the room (walls, ceilings, floors, doors, windows). The drawing shall also denote the type of current occupancy of adjacent areas to include areas of concern above and below the x−ray room (e.g., hallways, offices, parking lots and toilets). Estimates of the frequency of such occupancy shall also be noted on the drawing;

(g) A copy of all correspondence with this department regarding that x−ray machine.

(3) PLAN REVIEW. Prior to construction, the floor plans and equipment arrangement of all new installations or modifications of existing installations utilizing x−rays for diagnostic or therapeutic purposes shall be submitted to the department for review and approval.

(a) *Information on shielding required for plan review.* Two sets of plans shall be sent to the department's radiation protection unit for review and approval. The plans shall show, at minimum, the following:

1. The room and control booth dimensions.

2. The normal location of the radiation−producing equipment, tube head travel and traverse limits; general direction(s) of the primary radiation beam; locations of any windows; the location of the operator's booth and the location of the equipment's control console; location of any vertical cassette holder and table.

3. Structural composition and thickness of all walls, doors, partitions, floor and ceiling of the room(s) concerned.

4. Height, floor to floor, of the room(s) concerned.

5. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest existing occupied area(s).

6. The make and model of the radiation−producing equipment, including the maximum energy output which for x−ray machines is the kilovolt peak potential.

7. The anticipated workload and the type of examination(s) or treatment(s) which will be performed with the equipment (e.g., dental, orthodontic, chest, gastrointestinal, fluoroscopic, podiatry, fixed therapy, rotational therapy, etc.).

8. A copy of any report done by a qualified expert concerning the plans for shielding requirements.

(b) *Minimum design requirements.* 1. 'Machine operator's booth.' a. The booth shall be no closer than 1.3 meters from the nearest vertical cassette holder or .3 meters from the nearest corner of the examining table.

b. The booth walls shall be at least 2.1 meters high and shall be permanently fixed to the floor or other structure as may be necessary for general purpose radiography.

c. When a door or movable panel is used as an integral part of the booth structure, it shall have a permissive device which will prevent an exposure when the door panel is not closed.

2. 'Exposure switch placement.' a. The exposure switch shall be at least 1 meter from any open edge of the booth wall which is proximal to the examining table.

b. The exposure switch shall be fixed within the booth.

c. The exposure switch shall allow the operator to use the majority of the available viewing windows.

3. 'Viewing system requirements.' a. Each booth shall have at least one viewing device.

b. The device shall be so placed that the operator can have full view of any occupant of the room and shall be so placed that the operator can view any entry into the room. If any door, which allows access to the room, cannot be seen from the booth, then that door shall have a permissive device which will prevent the exposure if the door is not closed.

c. When the viewing device is a window, the following requirements also apply: the viewing device shall have a visible area of at least 0.09 square meters; the distance between the proximal edge of the window and the open edge of the booth shall not be less than .45 meters; the glass shall have the same lead equivalence as that required in the booth's wall in which it is to be mounted.

d. When the viewing is by mirror(s), the mirror(s) shall be so located as to accomplish the general requirements as in subd. 3. c.

e. When the viewing system is by electronic means, for example, television, the camera shall be so located as to accomplish the general requirements in subd. 3. c.

(c) *Modifications.* The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in s. HSS 157.12 (2) (a) and (e).

(4) PROCESSING OF FILM. All films shall be processed in such a fashion as to achieve maximum diagnostic information at the minimum exposure value. This criterion shall be adjudged to have been met if the film processing (chemical or equipment) manufacturer's recommendations are followed.

(5) ACTION BY THE DEPARTMENT. Within 30 days after receiving a complete application for registration and within 60 days after receiving a complete plan for approval under this chapter, the department shall register the installation or equipment or approve or deny approval to the plan and, in the case of the plan, shall

inform the person in control or other person submitting the plan of that decision.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82; cr. (5), Register, November, 1985, No. 359, eff. 12–1–85; correction in (3) (b) 3. made under s. 13.93 (2m) (b) 1., Stats., Register, August, 1995, No. 476**; correction in (3) (a) (intro.) made under s. 13.93 (2m) (b) 6., Stats., Register, March, 1996, No. 483.**

HSS 157.035 Registration fee. (1) In this section, "site" means street address.

(2) This section establishes fees for the annual registration of ionizing radiation installations. Pursuant to s. 254.35(3)(g), Stats., the fees in this section replace the fees set out in s. 254.35(3)(a) to (f)., Stats.

(3) An annual registration fee under this section shall be levied for each site, as follows:

(a) For a medical, chiropractic, podiatric, veterinary, industrial, school, research project or other non–dental site having an ionizing radiation installation or radioactive materials in any quantity, the annual fee shall be as follows:

1. For the calendar year beginning January 1, 1996, to December 31, 1996, $32 for the site and $39 for each x–ray tube at the site; and

2. Beginning January 1, 1997, $36 for each site and $44 for each x–ray tube at the site.

(b) For a dental site having an ionizing radiation installation, the annual fee shall be as follows:

1. For the calendar year beginning January 1, 1996 to December 31, 1996, $32 for the site and $26 for each x–ray tube at the site; and

2. Beginning January 1, 1997, $36 for each site and $30 for each x–ray tube at the site.

(4) The annual registration fee for the next year shall be paid by December 31 of the prior year of registration, and following receipt of the registration fee the department shall issue a new notice of registration. If the annual registration fee for the next year is not received by the department by December 31 of the prior year of registration, the department shall require payment of a penalty fee of $25, in addition to the registration fee and regardless of the number of x–ray tubes, before issuing the new notice of registration.

(5) Any change in registration information shall be submitted to the department within 30 days after the change takes place. There is no fee for recording changes in registration information.

History: Cr. Register, March, 1996, No. 483, eff. 4–1–96.

HSS 157.04 General requirements for all diagnostic x–ray systems. In addition to other requirements, all diagnostic x–ray systems shall meet the conditions specified in this section, many of which have been taken from 21 CFR 1020.30–31.

(1) WARNING LABEL. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x–ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) BATTERY CHARGE INDICATOR. On battery–powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(3) LEAKAGE RADIATION FROM THE DIAGNOSTIC SOURCE ASSEMBLY. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 100 milliroentgens in one hour when the x–ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(4) RADIATION FROM COMPONENTS OTHER THAN THE DIAGNOSTIC SOURCE ASSEMBLY. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x–ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(5) BEAM QUALITY. (a) *Half–value layer.* 1. The half–value layer (HVL) of the useful beam for a given x–ray tube potential shall not be less than the values shown in Table 157–B. If it is necessary to determine such half–value layer at an x–ray tube potential which is not listed in Table 157–B, linear interpolation or extrapolation may be made.

Table 157–B

MINIMUM HALF–VALUE REQUIREMENTS

X–ray tube voltage (kilovolt peak)		Minimum HVL (mm of Al)	
Designed operating range	**Measured operating potential**	**Specified dental systems**	**Other X–ray systems**
Below 50	30	1.5	0.3
	40	1.5	0.4
	49	1.5	0.5
50 to 70	50	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

2. Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.

3. For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

4. The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the focal spot of the tube and the patient. An example is a tabletop when the tube is mounted "under the table" and inherent filtration of the tube.

(b) *Filtration controls.* For x–ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and will prevent an exposure unless the minimum required amount of filtration (see Table 157–B) is in the useful beam for the given kVp which has been selected.

(6) MULTIPLE TUBES. Where 2 or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x–ray control and at or near the tube housing assembly which has been selected.

(7) MECHANICAL SUPPORT OF TUBE HEAD. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the x–ray system.

(8) TECHNIQUE INDICATORS. (a) *Variable technique factors.* The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated.

(b) *Fixed technique factors.* On equipment having fixed technique factors, the requirement in par. (a) may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82.

HSS 157.05 Fluoroscopic x–ray systems. All fluoroscopic x–ray systems shall meet the requirements of this section, many of which have been taken from 21 CFR 1020.32.

(1) LIMITATION OF USEFUL BEAM. (a) *Primary protective barrier.* The fluoroscopic tube shall not produce x–rays unless the primary protective barrier is in position to intercept the entire useful beam. The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any source–image receptor distance (SID).

(b) *Limitation to the imaging surface.* 1. The x–ray field produced by nonimage–intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic procedures and spot filming procedures.

2. During the fluoroscopic or spot filming procedures, neither the length nor the width of the x–ray field in the plane of the image receptor shall exceed the visible area of the image receptor by more than 3% of the SID (source to image distance). The sum of the excess length and the excess width shall be no greater than 4% of the SID. Compliance with this requirement shall be determined with the beam axis perpendicular to the image receptor. For rectangular x–ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x–ray field which pass through the center of the visible area of the image receptor.

3. Certified spot film devices shall also meet the following requirements:

a. Means shall be provided between the source and the patient for adjustment of the x–ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x–ray field size in the plane of the film is smaller than that of the selected portion of the film;

b. It shall be possible to adjust the x–ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum at the greatest SID, shall be equal to or less than 5 by 5 centimeters; and

c. The center of the x–ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2% of the SID.

(2) ACTIVATION OF THE FLUOROSCOPIC TUBE. X–ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x–ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) EXPOSURE RATE LIMITS. (a) The exposure measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens per minute, except during recording of fluoroscopic images or when provided with optional high level control.

(b) When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.

1. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use.

2. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(c) In addition to the other requirements of this section, certified equipment which does not incorporate an automatic exposure control (e.g., automatic brightness control or ionization chamber control) shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images or when provided with an optional high level control.

(d) Compliance with this subsection shall be determined as follows:

1. Movable grids and compression devices shall be removed from the useful beam during the measurement;

2. If the source is below the table, exposure rate shall be measured one centimeter above the tabletop or cradle;

3. If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam–limiting device or spacer positioned as closely as possible to the point of measurement;

4. In a C–arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(e) Periodic measurements of the entrance exposure rate shall be made.

1. An appropriate time for such measurements is immediately after any maintenance of the system which might affect the exposure rate.

2. Results of these periodic measurements shall be posted where any fluoroscopist may have ready access to them while using that fluoroscope and in the record required in s. HSS 157.03 (2) (e). Results of the measurements shall include the maximum possible R/minute, as well as the physical factors used to determine all data; the name of the person performing the measurements; and the date the measurements were performed.

3. The periodic measurements shall be made under the conditions that satisfy the requirements of par. (b).

4. The periodic measurements of the entrance exposure rate the kVp shall be the peak kV that the x–ray system is capable of producing.

5. For the periodic measurements of the entrance exposure rate the high level control, if present, shall not be activated.

6. For the periodic measurements of the entrance exposure rate the x–ray system(s) that incorporates automatic exposure control (automatic brightness control, etc.) shall have sufficient

material (e.g., lead or lead equivalence) placed in the useful beam to produce the maximum milliamperage of the x–ray system; and

7. The periodic measurements of the entrance exposure rate x–ray system(s) that do not incorporate automatic exposure control shall utilize the maximum milliamperage of the x–ray system. Materials such as an attenuation block may be placed in the useful beam to protect the imaging system.

(4) BARRIER–TRANSMITTED RADIATION RATE LIMITS. (a) *Transmission exposure rate.* The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(b) *Measuring compliance of barrier transmission.* 1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam–limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4. Movable grids and compression devices shall be removed from the useful beam during the measurement.

5. The attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(5) INDICATION OF POTENTIAL AND CURRENT. During fluoroscopy and cinefluorography, x–ray tube potential and current shall be continuously indicated.

(6) SOURCE–SKIN DISTANCE. Means shall be provided to limit the source–skin distance to not less than 38 centimeters on stationary fluoroscopes, to 35.5 centimeters on stationary fluoroscopes which are in operation prior to January 1, 1981, and to not less than 30 centimeters on mobile fluoroscopes. In addition, for image–intensified fluoroscopes intended for specific surgical–application that would be prohibited at the source–skin distances specified in this subsection, provisions may be made for operation at shorter source–skin distances but in no case less than 20 centimeters. The users operating manual must provide precautionary measures to be adhered to during the use of this device.

(7) FLUOROSCOPIC TIMER. Means shall be provided to preset the cumulative on–time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on–time. Such signal shall continue to sound while x–rays are produced until the timing device is reset. The timer may also terminate the radiation exposure.

(8) MOBILE FLUOROSCOPES. In addition to the other requirements of this section, mobile fluoroscopes shall provide intensified imaging.

(9) CONTROL OF SCATTERED RADIATION. (a) *Below table sources.* Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary person's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 mm lead equivalent.

(b) *Above table sources.* 1. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary person's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

a. Is at least 120 cm from the center of the useful beam; or

b. The radiation has passed through not less than 0.25 mm lead equivalent material (e.g., drapes, Bucky–slot covers, a sliding or folding panel, or self supporting curtains) in addition to any lead equivalency provided by the protective apron referred to in s. HSS 157.03 (1) (e) 2.

2. Exceptions to this paragraph may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the department shall not permit such exception.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82.

HSS 157.06 Intraoral dental radiographic systems.

This section establishes special requirements, many of them taken from 21 CFR 1020.32, for x–ray equipment and associated facilities used for intraoral dental radiography. These requirements are in addition to those in ss. HSS 157.03 and 157.04. Standards for extraoral dental radiographic systems are found in s. HSS 157.08.

(1) RADIOGRAPHIC EQUIPMENT. The provisions of this subsection apply to equipment for the recording of images, except those involving use of an image intensifier.

(a) *Source to skin distance.* X–ray systems designed for use with an intraoral image receptor shall be provided with means to limit source to skin distance to not less than:

1. Eighteen centimeters if operable above 50 kilovolts peak; or

2. Ten centimeters if not operable above 50 kilovolts peak.

(b) *Field limitation.* Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x–ray beam such that:

1. If the minimum source to skin distance (SSD) is 18 centimeters or more, the x–ray field, at the minimum SSD, shall be contained in a circle having a diameter of no more than 7 centimeters; and

2. If the minimum SSD is less than 18 centimeters, the x–ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.

3. Film holders that provide rectangular collimation limiting the useful beam to the area of the film should be used wherever feasible.

(c) *Timers.* Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

1. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero;

2. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided;

3. When 4 consecutive timer tests are performed at an identical timer setting in the range of normal utilization, the arithmetic mean (T) of the measured time periods must not be less than 5 times the difference between the maximum (T_{max}) and minimum (T_{min}) periods.

$$\left(\overline{\mathbf{T}}\mathrm{av} \geqq 5\left(\mathrm{T}_{\mathrm{max}}-\overline{\mathrm{T}}_{\mathrm{min}}\right)\right.$$

(d) *X–ray control (exposure switch).* 1. The actuating control shall be so designed that the exposure will be terminated at the end of the preset time interval or on release of pressure by the operator on the control.

2. Each x–ray control shall be located in such a way as to meet the following criteria:

a. To ensure that the operator is in a protected area during all exposures, the operating control switch shall be either perma-

nently mounted in a protected area (e.g., outside the room or in a shielded booth), or the operating control switch shall be mounted on a cord of sufficient length to allow easy operation from one or more protected areas. In the latter case the operating manual shall clearly define such areas and shall prescribe that operation should be limited to those areas. Floor or walls shall be marked as required for clear identification of protected areas.

b. Mobile and portable x–ray systems which are used for greater than one week in one location (one room or suite) shall meet the requirements of s. HSS 157.08 (2) (b) 2. a. Those systems used for more than one hour and less than one week at one location (one room or suite) shall meet the requirements of s. HSS 157.08 (2) (b) 2. b. and be provided with a 1.98 meters high protective barrier which is placed at least 1.83 meters from the tube housing assembly and at least 1.83 meters from the patient. Systems used to make an exposure(s) of only one patient at the use location shall meet the requirement of s. HSS 157.08 (2) (b) 2. b., or be provided with a method of control which will permit the operator to be at least 3.6 meters from the tube head assembly during an exposure.

3. The x–ray control shall provide visual indication observable at or from the operator's protected position whenever x–rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(2) EXPOSURE REPRODUCIBILITY. The exposure produced shall be reproducible to within the criteria in s. HSS 157.08 (4).

(3) OPERATING PROCEDURES. (a) *Holding devices.* Patient and film holding devices may be used as the technique requires or permits. Rectangular collimating filmholders should be used where feasible. The safety rules required by s. HSS 157.03 (1) (d) shall list conditions under which holding devices may not be utilized.

(b) *Hand–held equipment.* Neither the tube housing nor the attached beam orientation device shall be hand–held during an exposure.

(c) *Useful beam size.* The x–ray system shall be arranged and operated in such a manner that the useful beam at the patient's skin does not exceed the dimensions specified in sub. (1) (b) by more than 10%.

(d) *Dental fluoroscopy.* Dental fluoroscopy without image intensification is prohibited.

(4) ADDITIONAL REQUIREMENTS APPLICABLE TO CERTIFIED SYSTEMS ONLY. Only diagnostic x–ray systems incorporating one or more certified components shall be required to comply with the requirement(s) of this subsection which relate to that certified component in addition to other applicable requirements of these rules.

(a) *Reproducibility.* When the equipment is operated on an adequate power supply as specified by the manufacturer for any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05.

(b) *Linearity.* When the equipment allows a choice of x–ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with applicable federal standards for any fixed x–ray tube potential within the range of 40% to 100% of the maximum rated, the average ratios of exposure to the indicated milliampere–seconds product (mR/mAs) obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum. That is:

$$\overline{X}_1 - \overline{X}_2 \leqq 0.10(\overline{X}_1 + \overline{X}_2)$$

where $\overline{X}_1$ and $\overline{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

(c) *Accuracy.* Deviation of technique factors from indicated values shall not exceed the limits provided for that system by its manufacturer.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82.

HSS 157.07 Veterinary medicine radiographic installations. This section establishes requirements for the use of x–ray equipment in veterinary practice. The provisions of this section are in addition to and not in substitution for other applicable provisions of ss. HSS 157.12 and 157.19.

(1) EQUIPMENT. (a) The tube housing shall be shockproof and of a diagnostic type.

(b) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(c) Except when contraindicated for a particular radiographic purpose, the total filtration permanently in the useful beam shall not be less than 1.5 millimeters aluminum–equivalent for equipment operating up to 70 kVp and 2.5 millimeters aluminum–equivalent for machines operated in excess of 70 kVp.

(d) A device shall be provided to terminate the exposure after a pre–set time or exposure.

(e) A deadman type of exposure switch shall be provided, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam and at least 6 feet from the animal during all x–ray exposures.

(2) STRUCTURAL SHIELDING. All wall, ceiling and floor areas shall be equivalent to or provided with applicable protective barriers as required in s. HSS 157.12.

(3) OPERATING PROCEDURES. (a) *Operator location.* The operator shall stand well away from the tube housing and the animal during radiographic exposures. The operator shall not stand in the useful beam. If film must be held, it shall be held by individuals not occupationally exposed to radiation. Hand–held fluoroscopic screens shall not be used. The tube housing shall not be held by the operator. No individual other than the operator shall be in the x–ray room while exposures are being made unless such person's assistance is required.

(b) *Clothing.* 1. Unless measurements indicate otherwise, in any application in which the operator is not located behind a protective barrier, clothing consisting of a protective apron having a lead–equivalent of not less than 0.5 millimeter shall be worn by the operator and any other individuals in the room during exposures.

2. Any individual holding or supporting an animal or the film during radiation exposure shall wear protective gloves and apron having a lead–equivalent of not less than 0.5 millimeter.

(c) *Animal support.* No individuals shall be regularly employed to hold or support animals during radiation exposures. Operating personnel shall not perform this service except in cases in which no other method is available.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82.

HSS 157.08 Other radiographic systems. Radiographic systems other than fluoroscopic, dental intraoral or veterinarian systems shall meet the following requirements, many of which are taken from 21 CFR 1020.31:

(1) BEAM LIMITATION. The useful beam shall be limited to the area of clinical interest.

(a) *General purpose stationary and mobile x–ray systems.* 1. There shall be provided a means for stepless adjustment of the size of the x–ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 by 5 centimeters.

2. Means shall be provided for visually defining the perimeter of the x–ray field. The total misalignment of the edges of the visually defined field with the respective edges of x–ray field along either the length or width of the visually defined field shall not exceed 2% of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x–ray beam.

(b) *Additional requirements for stationary general purpose x−ray systems.* In addition to the requirements of par. (a) all stationary x−ray systems shall meet the following requirements.

1. Means shall be provided to indicate when the axis of the x−ray beam is perpendicular to the plane of the image receptor, to align the center of the x−ray field with respect to the center of the image receptor to within 2% of the SID, and to indicate the SID to within 2%;

2. The beam−limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

3. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in x−ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam−limiting device to within 2% of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

4. Compliance measurements shall be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 36, 40, 48 and 72 inches and nominal image receptor dimensions of 5, 7, 8, 9, 10, 11, 12, 14 and 17 inches) or at any other specific dimensions at which the beam−limiting device or its associated diagnostic x−ray system is uniquely designed to operate.

(c) *X−ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x−ray field with the center of the image receptor to within 2% of the SID.

(d) *Special purpose x−ray systems.* 1. Means shall be provided to limit the x−ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2% of the SID when the axis of the x−ray beam is perpendicular to the plane of the image receptor.

2. Means shall be provided to align the center of the x−ray field with the center of the image receptor to within 2% of the SID.

3. The requirements of subds. 1. and 2. may be met with a system that meets the requirements for a general purpose x−ray system as specified in par. (a), or, when alignment means are also provided, may be met with either:

a. An assortment of removable, fixed−aperture, beam−limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

b. A beam−limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(2) RADIATION EXPOSURE CONTROL DEVICES. (a) *Timers.* Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition,

1. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero; and

2. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(b) *X−ray control (exposure switch).* 1. A control shall be incorporated into each x−ray system such that an exposure can be terminated at any time except for:

a. Exposure of one−half second or less; or

b. During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

2. Each x−ray control shall be located in such a way as to meet the following criteria:

a. For stationary x−ray systems and for mobile and portable x−ray systems used for more than 30 days in one room, the control shall be permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure (See Appendix B).

b. For mobile and portable x−ray systems which are used for more than one hour but less than one month in one room, the control shall meet the requirement of subpar. a. or be provided with a 1.98 meters high protection barrier which is placed at least 1.83 meters from the tube housing assembly and at least 1.83 meters from the patient;

c. For mobile and portable x−ray systems which are used to make an exposure(s) on only one patient at the use location, the control shall meet the requirement of subpar. a. or be provided with a method of control which will permit the operator to be at least 3.6 meters from the tube head assembly during an exposure and the use of a lead apron is recommended in the latter case.

d. The x−ray control shall provide visual indication observable at or from the operator's protected position whenever x−rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(c) *Automatic exposure controls (phototimers).* When an automatic exposure control is provided:

1. Indication shall be made on the control panel when this mode of operation is selected;

2. When the x−ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

3. The minimum exposure time for all equipment other than that specified in subd. 2. shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;

4. Either the product of peak x−ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure or the product of x−ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x−ray tube potential is less than 50 kVp in which case the product of x−ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

5. A visible signal shall indicate when an exposure has been terminated at the limits described in subd. 4. and manual resetting shall be required before further automatically timed exposures can be made.

(d) *Reproducibility.* When 4 timer tests are performed, at identical timer settings, the average time period ($\overline{T}$) shall be greater than 5 times the maximum period (T_{max}) less the minimum (T_{min}). T shall be equal to or less than 0.5 seconds.

$$\overline{T} > 5\,(T_{max} - T_{min})$$

(3) SOURCE TO SKIN OR RECEPTOR DISTANCE. All radiographic systems shall be provided with a durable, securely fastened means to limit the source to skin distance to not less than 30 centimeters. This can be met when the collimator or cone provides the required limits.

(4) EXPOSURE REPRODUCIBILITY. The exposure produced shall be reproducible to within the following criteria: When all technique factors are held constant, the coefficient of variation shall not exceed 0.10. This shall be deemed to have been met if when 4 exposures at identical technique factors are made, the value of

the average exposure ($\overline{E}$) is greater than 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}).

$$\overline{E} > 5\,(E_{max}–E_{min})$$

(5) STANDBY RADIATION FROM CAPACITOR ENERGY STORAGE EQUIPMENT. Radiation emitted from the x–ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam–limiting device fully open.

(6) ADDITIONAL REQUIREMENTS APPLICABLE TO CERTIFIED SYSTEMS ONLY. Diagnostic x–ray systems incorporating one or more certified components shall comply with the following requirement(s) which relate to that certified component in addition to other applicable requirements.

(a) *Reproducibility.* When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with applicable federal standards, the estimated coefficient of variation of radiation exposures for any specific combination of selected technique factors shall be no greater than 0.5.

(b) *Linearity.* When the equipment allows a choice of x–ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with applicable federal standards for any fixed x–ray tube potential within the range of 40% to 100% of the maximum rated, the average ratios of exposure to the indicated milliampere–seconds product (mR/mAs) obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum. This is:

$$\overline{X}_1–\overline{X}_2 \leqq 0.10(\overline{X}_1 + \overline{X}_2)$$

where $\overline{X}_1$ and $\overline{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

(c) *Accuracy.* Deviation of technique factors from indicated values shall not exceed the limits provided for that system by its manufacturer.

(d) *Beam limitation for stationary and mobile general purpose x–ray systems.* 1. When a light localizer is used to define the x–ray field, it shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.

2. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam–limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam–limiting devices designed for use on mobile equipment. The contrast ratio is defined as l1/l2 where l1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and l2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture (diameter) of 1 millimeter.

(e) *Beam limitation.* Beam limitation for portable x–ray systems shall meet the field limitation requirements of par. (d) and sub. (1) (a).

(f) *Field limitation and alignment on stationary general purpose x–ray systems.* 1. Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x–ray field in the plane of the image receptor to the image receptor size within 5 seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than 5 seconds or is manual, will prevent production of x–rays until such adjustment is completed. At SIDs at which the device is not intended to operate, the device shall prevent the production of x–rays.

2. The x–ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x–ray field differs from that of the image receptor by greater than 3% of the SID and that the sum of the length and width differences without regard to sign be no greater than 4% of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

3. The radiographic system shall be capable of operation, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of 100 centimeters shall be equal to or less than 5 by 5 centimeters. Return to positive beam limitation as defined in subds. 1. and 2. shall occur upon a change in image receptor.

4. Positive beam limitation may be bypassed when radiography is conducted which does not use the cassette tray or permanently mounted vertical cassette holder, or when either the beam axis or table angulation is not within 10º of the horizontal or vertical during any part of the exposure, or during stereoscopic radiography. If the bypass mode is provided, return to positive beam limitation shall be automatic.

5. A capability may be provided for overriding positive beam limitation in the event of system failure or to perform special procedures which cannot be performed in the positive mode. If so provided, a key shall be required to override the positive mode. It shall be impossible to remove the key while the positive mode is overridden.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82.

HSS 157.09 Therapeutic x–ray systems of less than 1 MeV. (1) EQUIPMENT. Therapeutic x–ray equipment of less than 1 MeV shall have the following features:

(a) The tube housing shall be shockproof and of therapeutic type.

(b) Permanent diaphragms or cones used for collimating the useful beam shall afford the same degree of protection as the tube housing. Adjustable or removable beam–defining diaphragms or cones shall transmit not more than 5% of the useful beam obtained at the maximum kilovoltage and with maximum treatment filter. (See Appendix A, Table 12.)

(c) Filters shall be secured in place to prevent them from dropping out during treatment. The filter slot shall be so constructed that the radiation escaping through it does not exceed one roentgen per hour at one meter, or, if the radiation from the slot is accessible to the patient, 30 roentgens per hour at 5 centimeters from the external opening.

(d) The x–ray tube shall be so mounted that it cannot turn or slide with respect to the aperture. A mark on the housing should show the location of the focal spot.

(e) Means shall be provided to immobilize the tube housing during stationary portal treatment.

(f) A timer shall be provided to terminate the exposure after a preset time regardless of what other exposure limiting devices are present.

(g) Equipment utilizing shutters to control the useful beam shall have a shutter position indicator on the control.

(h) There shall be on the control panel an easily discernible indicator which will give positive information as to whether or not the x–ray tube is energized.

(i) Lead rubber, lead foil, or other materials used for limiting the field, should transmit not more than 5% of the useful beam. (See Appendix A, Table 12.)

(j) The tube housing assembly shall be so marked externally that it is possible to determine the location of the focal spot to within 5 millimeters of the actual focal spot.

(k) Contact therapy tube housing assemblies shall have a removable shield of 1/2 mm lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port.

(L) The operator shall be able to terminate an exposure at any time.

(m) The control panel shall have:

1. An indication of whether electrical power is present and activation of the x−ray tube is possible;

2. An indication of whether x−rays are being produced;

3. Means for indicating kVp and x−ray tube current;

4. A timer showing remaining exposure time for an individual exposure; and

5. A locking device which will prevent unauthorized use of the x−ray system.

(n) When a control panel may energize more than one tubehead:

1. It shall be impossible to activate more than one tubehead during one time interval;

2. There shall be an indication at the control panel identifying which tubehead may be energized; and

3. There shall be an indication at the tubehead if that tubehead may be energized.

(o) There shall be means of determining the target to patient distance to within one centimeter.

(p) If exposures are controlled by a timer, that timer:

1. Shall permit the setting of exposure times as short as one second; and

2. Shall not permit an exposure if set at zero.

(q) Unless it is possible to bring the x−ray output to the prescribed exposure parameters within 5 seconds the entire useful beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing. The shutter shall be electrically operated from the control panel, and an indication of shutter position shall appear at the control panel.

(r) A beam monitoring device fixed in the useful beam is recommended to indicate any error due to incorrect filter, milliamperage, or kilovoltage, unless it introduces more filtration than is clinically acceptable.

(2) FACILITY DESIGN REQUIREMENTS. In addition to shielding adequate to meet requirements of s. HSS 157.12, the following treatment room design requirements are made:

(a) *Warning lights.* Treatment rooms to which access is possible through more than one entrance shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on."

(b) *Communications.* Provision shall be made for oral communication with the patient from the control room.

(c) *Viewing systems.* Windows, mirror systems, or closed−circuit television viewing screens or an equivalent system shall be provided to permit continuous observation of the patient during treatment and shall be so located that the operator may see the patient and the control panel from the same position. When the viewing system is by electronic means (e.g. television) and an alternate viewing system is not available, treatment shall be immediately terminated if there is a viewing system failure.

(d) *Systems energies greater than 150 kVp.* Systems which may be operated above 150 kVp shall:

1. Have all necessary shielding (except for any beam interceptor) provided by fixed barriers;

2. The control panel shall be in a protected area which is outside the treatment room or which has a door electrically connected to the control panel in such a fashion that the door must be closed during x−ray production;

3. Have all doors or barriers of the treatment room electrically connected to the control panel such that the door(s) of the treatment room must be closed during x−ray production;

4. If the doors referred to in subds. 2. and 3. are opened when the therapy tubehead is activated, either the machine shall shut off within 2 seconds or the radiation at a distance of one meter from the target shall be reduced to 10 mR/hr or less within 2 seconds; and

5. If the radiation output of the tubehead is affected by any door opening, it shall be possible to restore the machine to full operation only by resetting the door, and subsequently reinitiating the exposure by action at the control panel.

(3) OPERATING PROCEDURES. (a) *Protection survey.* All new facilities, and existing facilities not previously surveyed, shall have a radiation protection survey made by or under the direction of a qualified expert. This shall also be done after any change in the facility which might produce a radiation hazard. The expert shall report the findings in writing to the person in charge of the facility and a copy of this report shall be transmitted by the facility to the department.

(b) *Calibrations.* The radiation output of each therapeutic x−ray machine shall be calibrated by or under the direction of a qualified expert who is physically present at the facility. The calibration shall be repeated after any change in or replacement of components of the x−ray generating equipment which could cause a change in x−ray output. In addition:

1. Systems with a peak kilovoltage of 150 kVp or less shall have the required calibrations repeated at time intervals not exceeding one year.

2. Systems capable of operation at kilovoltages greater than 150 kVp:

a. Shall have a repeat calibration at time intervals not exceeding one year;

b. Shall have spot checks performed at monthly intervals or after each 50 operating hours, whichever is the longer time interval. The spot check calibration shall be performed by a qualified expert or shall be performed in accordance with specifications which were designed by a qualified expert. Spot check specifications and results shall be maintained by the facility; and

c. When an abnormal output is determined by a spot check calibration, a full calibration procedure shall be performed on the x−ray system by a qualified expert.

(c) *Useful beam port.* In the therapeutic application of apparatus constructed with beryllium or other low−filtration windows, the persons in control shall assure that the unfiltered radiation reaches only the part intended and that the useful beam port is blocked at all times except when actually being used.

(d) *Unauthorized use.* Therapeutic x−ray machines shall not be left unattended unless the locking device required by sub. (1) (m) 5., is set to prevent use of the x−ray system.

(e) *Occupancy of treatment room.* No individual other than the patient shall be in the treatment room during exposures unless that individual is protected by a barrier sufficient to meet the requirements of s. HSS 157.12 (2) (a), and no individual other than the patient shall be in the treatment room when the kVp exceeds 50 during exposures.

History: Cr. Register, September, 1982, No. 321, eff. 10−1−82**; correction in (3) (d) made under s. 13.93 (2m) (b) 7., Stats., Register, March, 1996, No. 483**.

HSS 157.10 X−ray and electron therapy systems of 1 MeV and above. In addition to the requirements of this section, all subsections of s. HSS 157.14 except s. HSS 157.14 (3) (f) 3. and 4. shall apply to medical facilities using medical therapy equipment with energies 1 MeV and above.

(1) EQUIPMENT REQUIREMENTS. (a) *Leakage radiation to the patient area.* Where radiation leakage may be a hazard the department may, by specific order, impose upon the person in control such additional requirements as it deems appropriate or necessary to protect health or minimize danger to life or property. When imposing such additional requirements, the department will give due consideration to accepted standards of safe practice.

(b) *Beam limiting devices.* The primary collimating system shall transmit not more than 5% of the useful beam. Neutrons are not included in this requirement.

(c) *Filters.* In equipment which permanently incorporates interchangeable field–flattening filters or beam–scattering filters, irradiation shall not be possible until a selection of filter has been made at the treatment control panel and an interlock system shall be provided to prevent irradiation if the filter is not in the correct position.

(d) *Beam monitors.* Particle accelerator equipment shall be provided with at least one integrating radiation detector in the radiation head and should have 2 or more.

1. The detectors shall be removable only with tools or shall be interlocked to prevent incorrect positioning.

2. Each detector shall be capable of independently monitoring and terminating the useful beam.

3. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

4. For equipment with the design of 2 or more dose monitoring systems of subd. 3., the design shall assure that the malfunctioning of one system shall not affect the correct functioning of the second system. In addition:

a. The failure of any element which may be common to the systems shall terminate the useful beam and shall store the accumulated dose data in the event of a power failure;

b. The failure of the power supply of the system shall terminate the useful beam;

c. In the event that the primary dose system fails to terminate exposure, the secondary dose system, which shall be set at a reasonable number of monitor units above the primary dose system, shall terminate exposure. A termination fault shall occur when the secondary monitor terminates the exposure and should occur whenever the differences in dose rate between the channels exceeds 5%; and

5. Each dose monitoring system shall have a legible display at the treatment control panel. At least one shall maintain a reading until intentionally reset to zero. Each shall have only one scale and no scale multiplying factors.

(e) *Selection and display of dose monitor units.* 1. Irradiation shall not be possible until a dose monitor unit setting has been made at the treatment control panel.

2. After useful beam termination it shall be necessary to reset the dose monitor unit setting, before treatment can be reinitiated.

3. The monitor unit setting shall be displayed at the treatment control panel until reset for the next irradiation.

(f) *Termination switches.* It shall be possible to terminate irradiation and equipment movement at any time from the treatment control panel.

(g) *Timer.* 1. Except in special circumstances, a timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

2. Except in special circumstances, the timer shall be a cumulative timer which switches on and off with the radiation and retains its reading after irradiation is interrupted or terminated. It shall be necessary to zero the elapsed time indicator after radiation is terminated.

3. Except in special circumstances, the timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.

(h) *Selection of radiation type.* In equipment capable of both x–ray therapy and electron therapy:

1. Irradiation shall not be possible until a selection of radiation type (x–rays or electrons) has been made at the treatment control panel;

2. An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected; and

3. The radiation type selected shall be displayed at the treatment control panel before and during irradiation, and until reset for the next exposure.

(i) *Selection of energy.* In equipment capable of generating radiation beams of different energies:

1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. An interlock system shall be provided to insure that the equipment can emit only the energy of radiation which has been selected; and

3. The energy selected shall be displayed at the treatment control panel before and during irradiation.

(j) *Selection of stationary beam therapy or moving beam therapy.* In equipment capable of both stationary beam therapy and moving beam therapy:

1. Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel;

2. An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected;

3. An interlock system shall be provided to terminate irradiation if the movement stops during moving beam therapy;

4. Moving beam therapy shall be so controlled that the required relationship between the number of dose monitor units and movement is obtained; and

5. The mode of operation shall be displayed at the treatment control panel.

(2) FACILITY AND SHIELDING REQUIREMENTS. The following design requirements are in addition to shielding adequate to meet requirements of this section:

(a) *Barriers.* Except for entrance door and retractable beam stoppers, all the required barriers shall be fixed barriers. Interlocks shall be provided when retractable beam stoppers are used to meet the shielding requirements for adequate protection in accordance with s. HSS 157.12.

(b) *Control panel.* The control panel shall be located outside the treatment room.

(c) *Viewing systems.* Windows, mirror systems, closed–circuit television viewing screens or other equivalent viewing systems shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may see the patient and the control panel from the same position.

(3) OPERATING PROCEDURES. (a) *Protection survey.* 1. All new facilities, and existing facilities not previously surveyed, shall have a radiation protection survey made by a qualified expert. This shall also be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

2. The person in control shall obtain a written report of the survey from the qualified expert and a copy of the report shall be transmitted by the person in control to the department.

(b) *Exclusion of non–patient.* No person other than the patient shall be in the treatment room during treatment.

(c) *Calibrations.* The output of each therapeutic x–ray machine shall be calibrated by a qualified expert before it is first used for medical purposes. Calibrations shall be repeated at least once every 6 months and after any change which might significantly change the calibration or spatial distribution or other characteristics of the machine output. Calibration of the therapy beam shall be performed with a measurement instrument the calibration of which is directly traceable to national standards of exposure or absorbed dose, and which shall have been calibrated within the preceding 2 years. Check sources should be used daily to determine that the radiation measuring instrument is operating properly. Records of calibrations shall be maintained by the person in control.

(d) *Spot checks.* 1. A spot check shall be made at least weekly and shall include carefully selected representative or indicative measurements which will demonstrate the consistency of relevant machine operating characteristics, or lack of same.

2. The spot check methods shall be in writing and shall have been designed by a qualified expert.

3. Whenever a spot check indicates a significant change in the operating characteristics of a machine, the machine shall be recalibrated.

4. A log shall be kept of all spot check measurements.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82.

HSS 157.11 Use of sealed radioactive sources for treatment in the healing arts. (1) SCOPE. This section applies to all persons in control who use sealed sources in the healing arts. The requirements of this section are in addition to, and not in substitution for, other applicable provisions of this chapter.

(2) INTERSTITIAL, INTERCAVITARY AND SUPERFICIAL APPLICATIONS. (a) *Accountability, storage and transit.* 1. Except as otherwise specifically authorized by the department, each person in control shall be accountable for sealed sources and shall keep a record of the issue and return of all sealed sources. A physical inventory shall be made at least every 6 months and a written record of the inventory maintained.

2. When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to assure compliance with the provisions of s. HSS 157.12 (2) (a), (d) and (e).

(b) *Testing sealed sources for leakage and contamination.* 1. All sealed sources with a half–life greater than 30 days and in any form other than gas shall be tested for leakage and contamination prior to initial use and at intervals not to exceed 6 months. For sealed radium sources the intervals shall not exceed 12 months. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.

2. Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours. Any test conducted pursuant to subd. 1., which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The person in control shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of s. HSS 157.12.

3. Leak test results shall be recorded in units of microcuries and maintained for inspection by the department.

(c) *Radiation surveys.* 1. The maximum radiation level at a distance of one meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation and preferably by both. This radiation level shall be entered on the patient's chart and other signs as required under par. (d).

2. The radiation levels in the patient's room and the surrounding area shall be determined, recorded and maintained for inspection by the department.

(d) *Signs and records.* 1. In addition to the requirements of s. HSS 157.12 (3) (c), the bed, cubicle or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instruction. A sign is not required provided the exception in s. HSS 157.12 (3) (d) is met.

2. The following information shall be included in the patient's chart:

a. The radionuclide administered, number of sources, activity in millicuries and time and date of administration;

b. The exposure rate at one meter, the time the determination was made, and by whom;

c. The radiation symbol; and

d. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under s. HSS 157.12 (2) (a).

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82.]

HSS 157.12 Standards for protection against radiation. (1) PURPOSE AND SCOPE. This section establishes standards for protection against radiation hazards. Except as otherwise specifically provided, the section applies to all persons in control. Substantial portions of the section have been taken from 10 CFR 20. Nothing in this section shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or therapy. In addition to complying with the specific requirements set forth, persons in control should make every reasonable effort to restrict radiation exposure and the release of radioactive materials in effluents to unrestricted areas as far below the limits specified as practicable. "As far below the limits specified as practicable" means as low as is practicably achievable taking into account the state of technology and the economics of improvements in relation to benefits to the public health and safety and in relation to the utilization of ionizing radiation in the public interest.

(2) PERMISSIBLE DOSES, LEVELS AND CONCENTRATIONS. (a) *Limits on exposure to radiation in restricted areas.* For determining the doses specified in this paragraph, a dose from x or gamma rays up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.

1. Except as provided in subd. 2., no person in control shall possess, use, receive or transfer sources of radiation in such a manner as to cause any individual in a restricted area to receive in any period of one calendar quarter from all sources of radiation in the person in control's possession a dose in excess of the limits specified in Table 157–C:

Table 157–C

MAXIMUM PERMISSIBLE EXPOSURE TO RADIATION FOR OCCUPATIONAL WORKERS IN A NON–EMERGENCY SITUATION

Part of Body	Rem per Calendar Quarter
Whole body; head and trunk; active blood–forming organs; lens of eyes; or gonads . . .	$1\frac{1}{4}$
Hands and forearms; feet and ankles	$18\frac{3}{4}$
Skin of whole body	$7\frac{1}{2}$

2. A person in control may permit an individual in a restricted area to receive a dose to the whole body greater than that permitted under subd. 1., provided:

a. During any calendar quarter the dose to the whole body from sources of radiation in the person's in control possession shall not exceed 3 rem;

b. The dose to the whole body, when added to the accumulated occupational dose to the whole body, shall not exceed 5 (N–18) rem where "N" equals the individual's age in years at the individual's last birthday; and

c. The person in control has determined the individual's accumulated occupational dose to the whole body on department Form Rad A (Appendix C) or on a clear and legible record containing all the information required in that form and has otherwise com-

plied with the requirements of par. (b). As used in this subdivision, "dose to the whole body" shall be deemed to include any dose to the whole body, gonads, active blood–forming organs, head and trunk, or lens of eye.

(b) *Criteria for exposure in excess of the limits.* 1. This paragraph contains requirements which must be satisfied by persons in control who propose, pursuant to par. (a) 2. to permit individuals in a restricted area to receive exposure to radiation in excess of the limits specified in par. (a) 1.

2. Before permitting any individual in a restricted area to be exposed to radiation in excess of the limits specified in par. (a) 1., each person in control shall:

a. Obtain a certificate on department Form Rad A or on a clear and legible record containing all the information required in that form, signed by the individual, showing each period of time after the individual attained the age of 18 in which the individual received an occupational dose of radiation; and

b. Calculate on department Form Rad A in accordance with the instructions appearing therein, or on a clear and legible record containing all information required in that form, the previous accumulated occupational dose received by the individual and the additional dose allowed for that individual under par. (a) 2.

3. a. In the preparation of department Form Rad A or a clear and legible record containing all the information required in that form, the person in control shall make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the person in control obtains such reports, the person in control shall use the dose shown in the report in preparing the form. In any case where a person in control is unable to obtain reports of the individual's occupational dose for a previous complete calendar quarter, it shall be assumed that the individual has received the occupational dose specified in whichever of the following columns applies:

	Column 1	Column 2
Part of Body	**Assumed Dose in Rem for Calendar Quarters Prior to January 1, 1961**	**Assumed Dose in Rem for Calendar Quarters Beginning on or After January 1, 1961**
Whole body, gonads, active blood–forming organs, head and trunk, lens of eye	$3^3/_4$	$1^1/_4$

b. The person in control shall retain and preserve records used in preparing department Form Rad A. If calculation of the individual's accumulated occupational dose for all periods prior to January 1, 1961, yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in par. (a) 2. b., the excess may be disregarded.

(c) *Exposure of individuals to airborne concentrations of radioactive material in restricted areas.* 1. No person in control shall possess, use, receive or transfer radioactive material in such a manner as to cause an individual in a restricted area to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Appendix D, Table I. "Expose" as used in this subsection means that the individual is present in an airborne concentration. No allowance shall be made for the use of protective clothing or equipment, or particle size, except as authorized by the department pursuant to subd. 3.

2. The limits given in Appendix D, Table 1, are based upon exposure to the concentrations specified for 40 hours in any period of 7 consecutive days. In any such period where the number of hours of exposure is less than 40, limits specified in the table may be increased proportionately. In any such period where the number of hours of exposure is greater than 40, limits specified in the table shall be decreased proportionately.

3. Except as authorized by the department pursuant to this subdivision, no allowance shall be made for particle size or the use of protective clothing or equipment in determining whether an individual is exposed to an airborne concentration in excess of the limits specified in Appendix D, Table I.

3g. The department may authorize a person in control to expose an individual in a restricted area to airborne concentrations in excess of the limits specified in Appendix D, Table I, upon receipt of an application demonstrating that the concentration is composed in whole or in part of particles of such size that such particles are not respirable and that the individual will not inhale the concentrations in excess of the limits established in Appendix D, Table 1. Each application shall include an analysis of particle sizes in the concentrations and a description of the methods used in determining the particle sizes.

3m. The department may authorize a person in control to expose an individual in a restricted area to airborne concentrations in excess of the limits specified in Appendix D, Table I, upon receipt of an application demonstrating that the individual will wear appropriate protective equipment and that the individual will not inhale, ingest or absorb quantities of radioactive material in excess of those which might otherwise be permitted under this section for individuals in restricted areas during a 40–hour week. Each application shall contain:

a. A description of the protective equipment to be employed, including the efficiency of the equipment for the material involved;

b. Procedures for the fitting, maintenance and cleaning of the protective equipment;

c. Procedures governing the use of the protective equipment, including supervisory procedures and length of time the equipment will be used by the individuals in each work week. The proposed periods for use of the equipment by any individual should not be of such duration as would discourage observance by the individual of the proposed procedures; and

d. The average concentrations present in the areas occupied by individuals.

(d) *Exposure of minors.* For determining the doses specified in this paragraph, a dose from x or gamma rays up to 10 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.

1. No person in control shall possess, use or transfer sources of radiation in such a manner as to cause any individual within a restricted area, who is under 18 years of age, to receive in any period of one calendar quarter from all sources of radiation in such person's in control possession a dose in excess of 10% of the limits specified in the table in par. (a) 1.

2. No person in control shall possess, use or transfer radioactive material in such a manner as to cause any individual within a restricted area, who is under 18 years of age, to be exposed to airborne radioactive material in an average concentration in excess of the limits specified in Appendix D, Table II. For purposes of this subdivision, concentrations may be averaged over periods not greater than a week.

3. The provisions of par. (c) 3. to 3m. shall apply to exposures subject to this paragraph.

(e) *Permissible levels of radiation exposure from external sources in unrestricted areas.* It is the intent of this paragraph to limit radiation levels so that it is unlikely that individuals in unrestricted areas would receive a dose to the whole body in excess of 0.5 rem in any one year. If in specific instances it is determined by the department that this intent is not met, the department may impose such additional requirements on the person in control as may be necessary to meet the intent.

1. Except as authorized by the department pursuant to subd. 2., no person in control shall possess, use or transfer sources of radiation in such a manner as to create in any unrestricted area

from such sources of radiation in the possession of the person in control:

a. Radiation levels which, if an individual were continuously present in the area, could result in the individual receiving a dose in excess of 2 millirem in any one hour; or

b. Radiation levels which, if an individual were continuously present in the area, could result in the individual receiving a dose in excess of 100 millirem in any 7 consecutive days.

2. Any person may apply to the department for proposed limits upon levels of radiation in unrestricted areas in excess of those specified in subd. 1., resulting from the applicant's possession or use of sources of radiation. Such applications should include information as to anticipated average radiation levels and anticipated occupancy times for each unrestricted area involved. The department may approve the proposed limits if the applicant demonstrates to the satisfaction of the department that the proposed limits are not likely to cause any individual to receive a dose to the whole body in any period of one calendar year in excess of 0.5 rem.

(f) *Concentration limits in effluent releases to unrestricted areas.* 1. A user of a radiation installation shall not possess, use or transfer radioactive material so as to release to an unrestricted area radioactive material in concentrations which exceed the limits specified in Appendix D, Table II. For purposes of this paragraph, concentrations may be averaged over a period not greater than one year.

2. For the purposes of this paragraph, the concentration limits in Appendix D, Table II shall apply at the boundary of the restricted area. The concentration of radioactive material discharged through a stack, pipe or similar conduit may be determined with respect to the point where the material leaves the conduit. If the conduit discharges within the restricted area, the concentration at the boundary may be determined by applying appropriate factors for dilution, dispersion, or decay between the point of discharge and the boundary.

3. In addition to limiting concentrations in effluent streams, the department may limit quantities of radioactive material released into air or water during a specified period of time if it appears that the daily intake of radioactive material from air, water or food by a suitable sample of an exposed population group, averaged over a period not exceeding one year, would otherwise exceed the daily intake resulting from continuous exposure to air or water containing 1/3 the concentration of radioactive material specified in Appendix D, Table II.

4. The provisions of this paragraph do not apply to disposal of radioactive material into sanitary sewerage systems, which is governed by sub. (4) (c).

(g) *Orders requiring furnishing of bioassay services.* Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the department may issue an order requiring a person in control to make available to the individual appropriate bioassay services and to furnish a copy of the reports of such services to the department.

(3) PRECAUTIONARY PROCEDURES. (a) *Surveys.* Each person in control shall make or cause to be made such surveys as may be necessary for the person in control to establish compliance with this section.

(b) *Personnel monitoring.* 1. Each person in control shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by, each individual 18 years of age or older who enters a restricted area under such circumstances that the individual receives, or is likely to receive, a dose in any calendar quarter in excess of 25% of the applicable value specified in sub. (2) (a) 1.

2. Each person in control shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by, each individual under 18 years of age who enters a restricted area under such circumstances that the individual receives, or is likely to receive, a dose in any calendar quarter in excess of 5% of the applicable value specified in sub. (2) (a) 1.

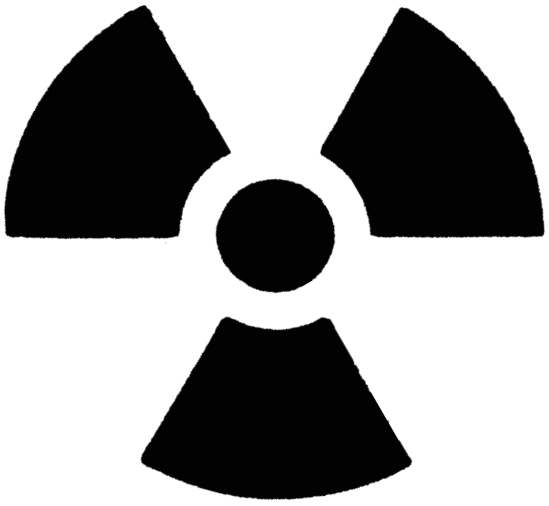
3. Each person in control shall supply appropriate personnel monitoring equipment for entry into a high radiation area, and shall require the use of such equipment by each individual who enters the area.

(c) *Caution signs, labels and signals in general.* 1. Except as otherwise authorized by the department, symbols prescribed in this subsection shall use the conventional radiation caution colors (magenta or purple on yellow background). The radiation symbol is the conventional three−blade design:

RADIATION SYMBOL

a. Cross−hatch area is to be magenta or purple.

b. Background is to be yellow.



2. Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION
RADIATION AREA

or

DANGER
RADIATION AREA

(d) *Caution signs, labels and signals in high radiation areas.* 1. Each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION
HIGH RADIATION AREA

or

DANGER
HIGH RADIATION AREA

2. Each entrance or access point to a high radiation area shall be:

a. Equipped with a control device which shall cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in one hour upon entry into the area; or

b. Equipped with a control device which shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering the high radiation area and the person in control or a supervisor of the activity are made aware of the entry; or

c. Maintained locked except during periods when access to the area is required, with positive control over each individual entry.

3. The controls required by subd. 2. b. shall be established in such a way that no individual will be prevented from leaving a high radiation area.

4. In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by subd. 2. b.

5. Any person in control may apply to the department for approval of methods not included in subds. 2. b. and 4., for controlling access to high radiation areas. The department shall approve the proposed alternatives if the person in control demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area, and that the requirements of this subdivision are met.

(e) *Caution signs, labels and signals in airborne radioactivity areas.* 1. Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION
AIRBORNE RADIOACTIVE AREA

or

DANGER
AIRBORNE RADIOACTIVE AREA

2. Each area or room in which any radioactive material is used or stored in an amount exceeding 10 times the quantity of radioactive material specified in Appendix E shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION
RADIOACTIVE MATERIAL

or

DANGER
RADIOACTIVE MATERIAL

3. Except as provided in subd. 3g., each container of radioactive material shall bear a durable, clearly visible label identifying the radioactive contents. The label shall bear the radiation caution symbol and the words:

CAUTION
RADIOACTIVE MATERIAL
or
DANGER
RADIOACTIVE MATERIAL

It shall also provide sufficient information to permit individuals handling or using the containers, or working in the vicinity thereof, to take precautions to avoid or minimize exposures. As appropriate, the information will include radiation levels, kinds of material, estimate of activity, date for which activity is estimated, etc.

3g. Notwithstanding the provision of subd. 3., labeling is not required:

a. For containers that do not contain radioactive material in quantities greater than the applicable quantities listed in Appendix E;

b. For containers containing only natural uranium or thorium in quantities no greater than 10 times the applicable quantities listed in Appendix E;

c. For containers that do not contain radioactive material in concentrations greater than the applicable concentrations listed in Column 2, Table I, Appendix D;

d. For containers when they are attended by an individual who takes the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established by this section;

e. For containers when they are in transport and packaged and labeled in accordance with regulations published by the United States department of transportation;

f. For containers which are accessible only to individuals authorized to handle or use them or to work in the vicinity thereof, (for example, containers in locations such as water−filled canals, storage vaults, or hot cells), provided that the contents are identified to such individuals by a readily available written record; and

g. For manufacturing and process equipment such as piping and tanks.

4. All radiation machines shall be labeled in a manner which cautions individuals that radiation is produced when the machine is being operated.

(f) *Exceptions from posting and labeling requirements.* 1. Notwithstanding the provisions of par. (c), a room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level 12 inches from the surface of the source container or housing does not exceed 5 millirem per hour.

2. Notwithstanding the provisions of par. (c), rooms or other areas in hospitals are not required to be posted with caution signs, and control of entrance or access thereto pursuant to par. (d), is not required because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in this section.

3. Notwithstanding the provision of par. (c), caution signs are not required to be posted in areas or rooms containing radioactive material for periods of less than 8 hours provided that the material is constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of any individual to radiation or radioactive material in excess of the limits established in this section, and such area or room is subject to the person in control's regulation.

4. Notwithstanding the provisions of par. (c), a room or other area is not required to be posted with a caution sign and control is not required for each entrance or access point when that room or other area is a high radiation area solely because of the presence of radioactive material prepared for transport and packaged and labeled in accordance with regulations of the United States department of transportation.

(g) *Instruction of personnel.* Instruction required for individuals working in or frequenting any portion of a restricted area are specified in s. HSS 157.19 (3).

(h) *Storage of sources of radiation.* Sources of radiation shall be secured against unauthorized removal from the place of storage.

(i) *Procedures for picking up, receiving and opening packages.* Each person in control shall establish and maintain procedures for safely opening packages in which radioactive material is received, and shall assure that such procedures are followed and due consideration is given to special instructions for the type of package being opened.

(4) WASTE DISPOSAL. (a) *General requirement.* This subsection applies to sources of radiation, except those sources licensed by the U. S. nuclear regulatory commission. No person in control shall dispose of any radioactive material or machine source except by transfer to an authorized person in control or as authorized pursuant to sub. (2) (f) and pars. (b) and (c) or (d).

(b) *Method of obtaining approval of proposed disposal procedures.* Any person may apply to the department for approval of

procedures to dispose of radioactive material in a manner not otherwise authorized. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and levels of radioactivity involved, and the proposed manner and condition of disposal.

(c) *Disposal by release into sanitary sewage systems.* 1. No person in control may discharge radioactive material into a sanitary sewerage system unless:

a. It is readily soluble or dispersible in water;

b. The quantity of any radioactive material released into the system by the person in control in any one day does not exceed the larger of sub. (2) (f) 1. or 3.; the quantity which, if diluted by the average daily quantity of sewage released into the sewer by the person in control, will result in an average concentration not greater than the limits specified in Appendix D, Table I, Column 2; or 10 times the quantity of such material specified in Appendix E;

c. The quantity of any radioactive material released in any one month, if diluted by the average monthly quantity of water released by the person in control, will not result in an average concentration exceeding the limits specified in Appendix D, Table I, Column 2; and

d. The gross quantity of radioactive material released into the sewerage system by the person in control does not exceed one curie per year.

2. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this subsection.

(d) *Disposal by burial in soil.* No person in control shall dispose of radioactive material by burial in soil unless he or she obtains prior written permission from the department.

(e) *Disposal by incineration.* No person in control may incinerate radioactive material for the purpose of disposal or preparation for disposal except as specifically approved by the department pursuant to sub. (2) (f) and par. (b).

(f) *Disposal by junking.* X−ray machine sources may be disposed of by junking, provided that the tube head is rendered inoperable and the person in control has made prior notification to the department. In addition, an x−ray machine source may be transferred or sold to an assembler, as defined in s. HSS 157.02 (10), upon notification to the department.

(5) RECORDS, REPORTS AND NOTIFICATION. (a) *Records of surveys, radiation monitoring and disposal.* 1. Each person in control shall maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under sub. (3) (b). Such records shall be kept on department Form Rad A, in accordance with the instructions contained in that form, or on clear and legible records containing all the information required by department Form Rad A. The doses entered on the forms or records shall be for periods of time not exceeding one calendar quarter.

2. Each person in control shall maintain records in the same units used in this section, showing the results of surveys required by sub. (3) (a), monitoring required by sub. (3) (b), and disposals made under sub. (4) (b), (c), and (d).

3. Records of individual exposure to radiation and to radioactive material which must be maintained pursuant to the provision of subd. 1., and records of bioassays, including results of whole body counting examinations, made pursuant to sub. (2) (g) shall be preserved indefinitely or until the department authorizes their disposal. Records which must be maintained may be in microform.

(b) *Reports of theft or loss of sources of radiation.* Each person in control shall report by telephone or telegraph to the department the theft or loss of any source of radiation immediately after such occurrence becomes known.

(c) *Notification of incidents.* 1. Each person in control shall immediately notify the department by telephone or telegraph of any incident involving any source of radiation possessed by the person in control which may have caused or threatens to cause:

a. A dose to the whole body of any individual of 25 rem or more of radiation; a dose to the skin of the whole body of any individual of 150 rem or more of radiation; or a dose to the feet, ankles, hands, or forearms of any individual of 375 rem or more of radiation; or

b. The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 5,000 times the limits specified for such materials in Appendix D, Table II; or

c. A loss of one working week or more of the operation of any facilities affected; or

d. Damage to property in excess of $100,000.

2. Each person in control shall within 24 hours notify the department by telephone or telegraph of any incident involving any source of radiation possessed by the person in control which may have caused or threatens to cause:

a. A dose to the whole body of any individual of 5 rem or more of radiation; a dose to the skin of the whole body of any individual of 30 rem or more of radiation; or a dose to the feet, ankles, hands, or forearms of 75 rem or more of radiation; or

b. The release of radioactive material in concentrations which, if averaged over a period of 24 hours, would exceed 500 times the limits specified for such materials in Appendix D, Table II; or

c. A loss of one day or more of the operation of any facility affected; or

d. Damage to property in excess of $1,000.

3. Any report filed with the department pursuant to this subsection shall be prepared in such a manner that names of individuals who have received excessive doses will be stated in a separate part of the report.

(d) *Reports of overexposures and excessive levels and concentrations.* 1. In addition to any notification required by par. (c), each person in control shall make a report in writing within 30 days to the department of:

a. Each exposure of an individual to radiation or concentrations of radioactive material in excess of any applicable limit or as otherwise approved by the department;

b. Any incident for which notification is required by par. (c); and

c. Levels of radiation or concentration of radioactive material (not involving excessive exposure of any individual) in an unrestrictive area in excess of 10 times any applicable limit or as otherwise approved by the department. Each report required shall describe the extent of exposure of individuals to radiation or to radioactive material, including estimates of each individual's dose as required by subd. 2.; levels of radiation and concentrations of radioactive material involved; the cause of exposure, levels or concentrations; and corrective steps taken or planned to assure against a recurrence.

2. Any report filed with the department pursuant to this subsection shall include for each individual exposed the name, social security number and date of birth and an estimate of the individual's dose. The report shall be prepared so that this personal information is stated in a separate part of the report.

(e) *Vacating premises.* Each specific person in control shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the person in control's activities, notify the department in writing of intent to vacate. When deemed necessary by the department, the person in control shall decon-

taminate the premises in such a manner as the department may specify.

(f) *Notifications and reports to individuals.* 1. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in s. HSS 157.19 (4).

2. When a person in control is required pursuant to par. (d) to report to the department any exposure of an individual to radiation or radioactive material, the person in control shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the department and shall comply with the provision of s. HSS 157.19 (4) (a).

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82; correction in (3) (e) made under s. 13.93 (2m) (b) 1., Stats., Register, August, 1995, No. 476**; corrections in (3) (f) 2. and (5) (a) 2. made under s. 13.93 (2m) (b) 7., Stats., Register, March, 1996, No. 483**.

HSS 157.13 Radiation safety requirements for analytical x–ray equipment. (1) PURPOSE AND SCOPE. This section provides special requirements for analytical x–ray equipment, and is based in part on 21 CFR 1020.20 and 1020.40. These requirements add to and do not substitute for other requirements of this chapter.

(2) EQUIPMENT REQUIREMENTS. (a) *Safety device.* A device which prevents the entry of any portion of an individual's body into the primary x–ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open–beam configurations, except that the person in control may apply to the department for an exemption from the requirement of a safety device. Such application shall include:

1. A description of the various safety devices that have been evaluated;

2. The reason each of these devices cannot be used; and

3. A description of the alternative methods to be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) *Warning devices.* Open–beam configurations shall be provided with a readily discernible indication of:

1. X–ray tube status (ON–OFF) located near the radiation source housing, if the primary beam is controlled in this manner; or

2. Shutter status (OPEN–CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner. Warning devices shall be labeled so that their purpose is easily identified.

(c) *Ports.* Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(d) *Labeling.* All analytical x–ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

1. "CAUTION – HIGH INTENSITY X–RAY BEAM," or words having a similar intent, on the x–ray source housing; and

2. "CAUTION RADIATION – THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x–ray tube if the radiation source is an x–ray tube; or

3. "CAUTION – RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing if the radiation source is a radionuclide.

(e) *Shutters.* On open–beam configurations installed after January 1, 1979, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(f) *Warning lights.* An easily visible warning light labeled with the words "X–RAY ON," or words having a similar intent, shall be located:

1. Near any switch that energizes an x–ray tube and shall be illuminated only when the tube is energized; or

2. In the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.

(g) *Radiation source housing.* Each x–ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 mrem in one hour at any specified tube rating.

(h) *Generator cabinet.* Each x–ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem in one hour.

(3) AREA REQUIREMENTS. (a) *Radiation levels.* The local components of an analytical x–ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to any individual in excess of the dose limits given in s. HSS 157.12 (2) (a). For systems utilizing x–ray tubes, these levels shall be met at any specified tube rating.

(b) *Surveys.* Radiation surveys, as required by s. HSS 157.12 (3) (a) of all analytical x–ray systems sufficient to show compliance with par. (a) shall be performed:

1. Upon installation of the equipment;

2. Following any change in the initial arrangement, number or type of local components in the system;

3. Following any maintenance requiring the disassembly or removal of a local component in the system;

4. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x–ray beam when any local component in the system is disassembled or removed;

5. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits of s. HSS 157.12 (2) (a) 1., radiation survey measurements shall not be required if a person in control can demonstrate compliance to the satisfaction of the department with par. (a) in some other manner.

(c) *Posting.* Each area or room containing analytical x–ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION – X–RAY EQUIPMENT," or words having a similar intent.

(4) OPERATING REQUIREMENTS. (a) *Procedures.* Normal operating procedures shall be written and available to all analytical x–ray equipment workers. No person shall be permitted to operate analytical x–ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the person in control.

(b) *Bypassing.* No person shall bypass a safety device unless such person has obtained the approval of the person in control. When a safety device has been bypassed, a readily discernible sign bearing the words"SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

(5) PERSONNEL REQUIREMENTS. (a) *Instruction.* No person shall be permitted to operate or maintain analytical x–ray equipment unless such person has received instruction in and demonstrated competence as to:

1. Identification of radiation hazards associated with the use of the equipment;

2. Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have

not been installed on certain pieces of equipment and the extra precautions required in such cases;

3. Proper operating procedures for the equipment;

4. Symptoms of an acute localized exposure; and

5. Proper procedures for reporting an actual or suspected exposure.

(b) *Personnel monitoring.* Finger or wrist dosimetric devices shall be provided to and used by:

1. Analytical x−ray equipment workers using systems having an open−beam configuration and not equipped with a safety device; and

2. Personnel maintaining analytical x−ray equipment if the maintenance procedures require the presence of a primary x−ray beam when any local component in the analytical x−ray system is disassembled or removed. Reported dose values shall not be used for the purpose of determining compliance with s. HSS 157.12 (2) (a) unless the dose values are evaluated by a qualified expert.

History: Cr. Register, September, 1982, No. 321, eff. 10−1−82.

HSS 157.14 Radiation safety requirements for particle accelerators. (1) PURPOSE AND SCOPE. The purpose of this section is to establish procedures for the registration and the use of particle accelerators. These requirements are in addition to and not in substitution for other applicable requirements of this chapter.

(2) REGISTRATION PROCEDURE. (a) *Registration requirements.* No person shall receive, possess, use, transfer, own or acquire a particle accelerator except as authorized in a registration issued pursuant to these rules or as otherwise provided for in these rules. The general procedures for registration of particle accelerator facilities are included in s. 140.54, Stats.

(b) *General requirements for registration of particle accelerators.* In addition to the requirements of s. 140.54, Stats., a registration application for use of a particle accelerator shall be approved only if the department determines that:

1. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this section and ss. HSS 157.12 and 157.19 in such a manner as to minimize danger to public health and safety or property;

2. The applicant's proposed equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property. A floor plan shall be submitted to the department for approval prior to construction of the facility;

3. The issuance of the registration will not be detrimental to the health and safety of the public, and the applicant satisfies the requirements of par (c).

(c) *Human use of particle accelerators.* In addition to the requirements set forth in s. 140.54, Stats., a registration for use of a particle accelerator in the healing arts shall be issued only if the principal user designated on the registration has substantial training and experience in radiation therapy of human disease and is a physician.

(3) RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS. (a) *Limitations.* No person in control shall permit any person to act as a particle accelerator operator until such person has knowledge of radiation safety procedures; has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in the operator's assignment; and has reviewed this section and the applicable requirements of ss. HSS 157.12 and 157.19, pertinent registration conditions and the person in control's emergency procedures.

(b) *Shielding and safety design requirements.* 1. Floor plans indicating the shielding shall be submitted to the department for review and approval prior to construction of the accelerator facility.

2. A radiation survey shall be performed before scheduled use. This survey shall be performed by a qualified expert or at the option of the department shall be performed by the department. The results of this survey shall be submitted to the department by the person in control.

(c) *Particle accelerator controls and interlock system.* 1. Instrumentation, readouts and controls on the particle accelerator control console shall be clearly identified and easily discernible.

2. All entrances into a target room or other high radiation area shall be provided with interlocks that shut down the machine under conditions of barrier penetration.

3. When an interlock system has been tripped, it shall be possible to reactivate the beam only at the main control console.

4. All safety interlocks shall be fail−safe, that is, designed so that any defect or component failure in the interlock system prevents operation of the accelerator.

5. An easily identifiable emergency power cutoff switch shall be located in all high radiation areas.

(d) *Warning devices.* 1. Entrances to all locations designed as high radiation areas shall be equipped with easily observable warning lights that operate only when radiation is being produced.

2. Except in facilities designed for human radiation therapy, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the initiation of radiation. Such warning devices shall be clearly recognizable in all high radiation areas and all radiation areas.

3. Barriers, temporary or otherwise and pathways leading to high radiation areas shall be identified in accordance with s. HSS 157.12 (3) (c).

(e) *Operating procedures.* 1. Particle accelerators when not in operation shall be secured to prevent unauthorized use.

2. A switch only on the accelerator control console shall be routinely used to turn the accelerator beam on and off. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

3. All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed 6 months. Results of such tests shall be maintained for inspection at the accelerator facility.

4. A copy of the current operating and the emergency procedures shall be readily available.

(f) *Radiation monitoring requirements.* 1. There shall be available at each particle accelerator facility appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility.

2. A radiation protection survey shall be performed and documented by a qualified expert when changes have been made in shielding, operation, equipment or occupancy of adjacent areas.

3. In nontherapy use, radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and interlock systems and capable of providing a remote and local readout with visual or audible alarms or both, at both the control panel and at entrance to high radiation areas, and other appropriate locations, so that people entering or present become aware of the existence of the hazard.

4. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.

5. Whenever applicable, period smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.

6. All area surveys shall be made in accordance with procedures established by a qualified expert.

7. Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility.

(g) *Ventilation systems.* Adequate ventilation shall be provided in areas where airborne radioactivity may be produced so as to comply with s. HSS 157.12. For purposes of this subsection, concentrations may be averaged over a period not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to uncontrolled areas as far below these limits as practicable.

(h) *Decommissioning.* Thirty days prior to the decommissioning of each accelerator, the person in control must notify the department in writing. The department may require special surveys and other precautions as deemed necessary to ensure the safe dismantling of an accelerator and subsequent disposition of the unit in accordance with s. HSS 157.12.

History: Cr. Register, September, 1982, No. 321, eff. 10−1−82.

HSS 157.15 Radiation safety requirements for industrial radiographic operations. (1) INTRODUCTION. (a) *Purpose.* The purpose of this section is to establish radiation safety requirements for persons utilizing sources of radiation for industrial radiography. The requirements of this section are in addition to and not in substitution for other requirements of this chapter.

(b) *Applicability.* This section applies to all persons in control who use sources of radiation for industrial radiography, except that this section shall not apply to the use of sources of radiation in the healing arts.

(c) *Classification.* Industrial x−ray installations shall be classified as either class A, class B, class C or class D. This section includes radium and its decay products and appropriate requirements under each installation class shall be applied. Class A permits unlimited use at maximum capacity as specified by the person in control at the time of registration. Class B permits unlimited use under limited operating conditions as specified by the person in control at the time of registration. Class C permits limited use under conditions specified by the person in control at the time of registration. Class D permits limited use and temporary operation, including portable or mobile industrial x−ray installations.

(2) CLASS A INSTALLATION REQUIREMENTS AND OPERATING AND EMERGENCY PROCEDURES. (a) *Enclosure.* The x−ray source and the objects exposed to it must be contained within a permanent enclosure.

1. The enclosure shall be constructed:

a. So that the primary and secondary x−ray are attenuated to a dose rate as measured in air at any accessible external point not to exceed 2 milliroentgens per hour when the x−ray beam is adjusted to give maximum dose rate with the x−ray generator running at maximum operating conditions and the x−ray tube placed in the shortest "tube to wall" radiographically usable position. Mechanical or electrical limiters may be placed on the x−ray apparatus to restrict the movement of the beam to an area which will result in a dose rate not in excess of 2 milliroentgens per hour measured in air at any accessible point;

b. With reliable interlocks which will either prevent opening of the enclosure while the x−ray generator is in operation or will terminate the generation of x−rays should the enclosure be opened;

c. So that persons may at all times be able to escape from within the enclosure;

d. With visible or audible or both signals within the enclosure which are actuated a minimum of 5 seconds prior to the generation of x−rays; and

e. So that if the ceiling barrier does not attenuate the dose rate as set forth in this subsection, a posted barrier, such as a fence, shall be used to restrict access to the area having excessive dose rate.

2. No person is permitted to remain within the enclosure while the x−ray generator is in operation.

3. No x−ray apparatus or other radiographic sources shall be left unattended without locking the apparatus itself or the room or building in some manner which will prevent its use by unauthorized person.

4. All protective enclosures and equipment shall be kept in good repair.

(b) *Operating and emergency procedures.* 1. The person in control's operating and emergency procedures shall include instructions in at least the following:

a. Procedures for the handling and use of radium sources and radiographic exposure devices such that no person is likely to be exposed to radiation doses in excess of the limits specified in s. HSS 157.12 (2) (a) for restricted areas and s. HSS 157.12 (2) (e) for unrestricted areas;

b. The procedure for notifying the department and emergency agencies in event of accident or fire;

c. A procedure for minimizing exposure to persons in the event of an accident;

d. Methods and occasions for conducting radiation surveys;

e. Security procedures for use during each radiographic operation. Either the radiographer or the radiographer's assistant shall maintain direct vigilance of the operation to protect against unauthorized entry into high radiation area;

f. Personnel monitoring and the use of personnel monitoring equipment;

g. Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation; and

h. Minimizing exposure of individuals in the event of an accident.

2. The person in control shall make or cause to be made such surveys as may be necessary to determine compliance with this subsection. Records shall be kept of each survey for inspection by the department.

3. Loss of any radium source must be reported to the department within 24 hours of the discovery of the loss.

(3) CLASS B INSTALLATION REQUIREMENTS AND OPERATING AND EMERGENCY PROCEDURES. (a) *Operating conditions.* All provisions of sub. (1) apply when the x−ray source is operated under maximum normal operating conditions as specified by the person in control at the time of registration.

(b) *Controls.* The controls for the kilovoltage and milliamperage shall be limited by mechanical or electrical means so as not to exceed the maximum normal operating conditions as specified by the person in control at the time of registration.

(4) CLASS C INSTALLATION REQUIREMENTS AND OPERATING AND EMERGENCY PROCEDURES. (a) *Operating conditions.* All provisions of sub. (1) apply except that a dose rate of 50 milliroentgens per hour at accessible external points is allowable.

(b) *Operating limitations.* The number of hours per week for permissible operation shall be established for the x−ray generator by the department.

(c) *Warning signs.* Warning signs shall be posted in those areas outside the protective barriers in which the dose rate in air at any accessible external point exceeds 2 milliroentgens per hour with the generator operating at its maximum rated capacity and the x−ray beam adjusted to give its maximum dose rate and the x−ray tube placed in the shortest "tube to wall" usable or limited or both radiographic position. A visible or audible or both signal shall be provided within the posted area which shall be actuated during the generation of x−rays.

(d) *Personnel monitoring.* Film badges or other permanent recording instruments shall be provided and required to be worn continuously by persons in the posted area.

(5) CLASS D INSTALLATION REQUIREMENTS AND OPERATING AND EMERGENCY PROCEDURES. (a) *Operating restrictions.* An x−ray installation not meeting the conditions and specifications as described as class A, class B, or class C may be operated for a period not to exceed 30 days. When it is impractical or when an undue and unnecessary hardship is involved, such period may be extended by the department. In either case, such installation and operation of such installation must be approved by the department before use and shall be classified as a class D installation.

(b) *Unattended apparatus.* No x−ray apparatus or other radiographic sources shall be left unattended without locking the apparatus itself or the room or building in some manner which will prevent its use by unauthorized persons.

(c) *Exclusion area.* To exclude all unauthorized persons, all such installations shall have the radiation area in excess of 5 milliroentgens per hour posted and barricaded by a fence, rope, or other suitable personnel barriers erected outside the 5 milliroentgens per hour contour line.

(d) *Personnel monitoring.* Film badges or other permanent recording instruments shall be provided and required to be properly used on a continual basis for personnel in the posted area and such other personnel who might be specified by the department.

(e) *Required instrumentation.* A calibrated and operable survey instrument shall be assigned for each installation. Such instrument shall have a range such that 2 milliroentgens per hour through 1 roentgen per hour can be measured.

(f) *Registration.* 1. The initial registration shall be in the possession of the department prior to the approval of a radiographic source.

2. If the source has been previously registered, notification of a change in work address must be in the possession of the department prior to the approval of the source at any address other than that indicated on the registration form.

(g) *Operating and emergency procedures.* All provisions of sub. (2) (b) apply.

(6) CABINET X−RAY SYSTEMS. (a) *Applicability.* The provisions of this subsection are applicable to cabinet x−ray systems manufactured or assembled on or after April 10, 1975, except that the provisions as applied to x−ray systems designed primarily for the inspection of carry−on baggage are applicable to such systems manufactured or assembled on or after April 25, 1974. The provisions of this subsection are applicable to systems which are designed exclusively for microscopic examination of material, e.g., x−ray diffraction, spectroscopic and electron microscope equipment or to systems for intentional exposure of humans to x−rays. "Cabinet x−ray system" means an x−ray system with the x−ray tube installed in an enclosure (hereinafter termed"cabinet") which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x−rays. Included are all x−ray systems designed primarily for the inspection of carry−on baggage at airline, railroad and bus terminals and in similar facilities. An x−ray tube used within a shielded part of a building or x−ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x−ray system.

(b) *Requirements.* 1. Radiation emitted from the cabinet x−ray system shall not exceed an exposure of 0.5 milliroentgens in one hour at any point 5 centimeters outside the external surface. Compliance with the exposure limit shall be determined by measurements averaged over a cross−sectional area of 10 square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x−ray system operated at those combinations of x−ray tube potential, current, beam orientation and conditions of scatter radiation which produce the maximum x−ray exposure at the external surface and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x−rays.

2. A cabinet x−ray system shall have a permanent floor. Any support surface to which a cabinet x−ray system is permanently affixed may be deemed the floor of the system.

3. The insertion of any part of the human body through any port into the primary beam shall not be possible. The insertion of any part of the human body through any aperture shall not be possible.

4. Cabinet x−ray systems shall have the following interlocks:

a. Each door of a cabinet x−ray system shall have a minimum of 2 safety interlocks. One, but not both of the required interlocks shall be such that opening a door results in physical disconnection of the energy supply circuit to the high−voltage generator, and such disconnection shall not be dependent upon any moving part other than the door;

b. Each access panel shall have at least one safety interlock;

c. Following interruption of x−ray generation by the functioning of any safety interlock, use of a control provided in accordance with subd. 6. b. shall be necessary for resumption of x−ray generation; and

d. Failure of any single component of the cabinet x−ray system shall not cause failure of more than one required safety interlock.

5. A ground fault shall not result in the generation of x−rays.

6. For all systems to which this section is applicable, there shall be provided:

a. A key−actuated control to insure that x−ray generation is not possible with the key removed;

b. A control or controls to initiate and terminate the generation of x−rays other than by functioning of a safety interlock or the main power control;

c. Two independent means which indicate when and only when x−rays are being generated, unless the x−ray generation period is less than one−half second, in which case the indicators shall be activated for one−half second, and which are discernible from any point at which initiation of x−ray generation is possible. Failure of a single component of the cabinet x−ray system shall not cause failure of both indicators to perform their intended function. One, but not both of the indicators required by this subsection may be a milliampmeter labeled to indicate x−ray tube current. All other indicators shall be legibly labeled"X−RAY ON."

7. For cabinet x−ray systems designed to admit humans there shall also be provided:

a. A control within the cabinets for preventing and terminating x−ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet;

b. No means by which x−ray generation can be initiated from within the cabinet;

c. Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x−ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x−ray system shall not cause failure of both the audible and visible warning signals;

d. A visible warning signal within the cabinet which remains actuated when and only when x−rays are being generated, unless the x−ray generation period is less than one−half second in which case the indicators shall be activated for one−half second;

e. Signs indicating the meaning of the warning signals provided pursuant to subd. 7. c. and d. and containing instructions for the use of the control provided pursuant to subpar. a. These signs shall be legible, accessible to view and illuminated when the main power control is in the "on" position.

8. Warning labels shall be provided as follows:

a. There shall be permanently affixed or inscribed on the cabinet x–ray generator, a clearly legible and visible label bearing the statement: CAUTION: X–RAYS PRODUCED WHEN ENERGIZED; and

b. There shall be permanently affixed or inscribed on the cabinet x–ray system adjacent to each port a clearly legible and visible label bearing the statement: CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED — X–RAY HAZARD.

(c) *Additional requirements for x–ray baggage inspection systems.* X–ray systems designed primarily for the inspection of carry–on baggage at airline, railroad and bus terminals, and at similar facilities, shall be provided with means, pursuant to subds. 1. and 2., which insure operator presence at the control area in a position that permits surveillance of the ports and doors during generation of x–rays.

1. During an exposure or preset succession of exposures of one–half second or greater duration, the means provided shall enable the operation to terminate the exposure or preset succession of exposures at any time.

2. During an exposure or preset succession of exposures of less than one–half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

(7) INDUSTRIAL RADIUM INSTALLATION REQUIREMENTS AND OPERATING AND EMERGENCY PROCEDURES. Installations utilizing sealed radium sources, other than those covered under s. HSS 157.11, shall meet all appropriate requirements for radiological safety specified for x–ray installations of class A, class B, class C, or class D, whichever may be applicable.

(a) *Accountability and storage.* 1. Except as otherwise specifically authorized by the department, each person in control shall be accountable for sealed sources and shall keep a permanent record of the issuance and return of all sealed sources.

2. When not in use, sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to assure compliance with the provisions of s. HSS 157.12 (2) (a) and (e).

(b) *Source housing.* If the source is permanently mounted in a housing with a beam control device or extended from and retracted into a housing, this device shall be of positive design capable of acting in any position of the housing. It shall also be possible to move the source to a shielded position manually with a minimum risk exposure in the event of the failure of the automatic mechanism. There shall be on the housing and on the control panel a warning device which plainly indicates whether the apparatus is "on" or "off".

(c) *Source transfer devices.* If the apparatus is of a type in which the source is removed from the shield when in use, transfer shall be accomplished by a remote control mechanism. Transfer mechanisms shall be designed to minimize the possibility of damage to the source in transit.

(d) *Source locking.* Each radiographic exposure device shall be provided with a lock and stored within a locked enclosure designed to prevent unauthorized or accidental removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of authorized personnel.

(e) *Testing sealed sources for leaking and contamination.* 1. The person in control shall provide for testing for leakage and contamination prior to initial use. All sealed sources shall be tested for leakage at least every 12 months, unless otherwise specified by the department. If there is reason to suspect that a sealed source might have been damaged, it shall be tested for leakage before further use.

2. Leak tests shall be capable of detecting the presence of 0.005 microcuries of contamination of radium and its decay products. Any test conducted which reveals the presence of 0.005 microcuries or more of removable contamination shall be considered evidence that the sealed source is leaking. The person in control shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of.

(f) *Radiation survey requirements.* A radiation survey shall be made after each use to determine that the radium source has been returned to its shielded position. Records shall be kept of each survey for inspection by the department.

(8) EQUIPMENT CONTROL. (a) *Limits on levels of radiation for radiographic exposure devices and storage containers.* Radiographic exposure devices measuring less than 4 inches from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens per hour at 6 inches from any exterior surface of the device. Radiographic exposure devices measuring a minimum of 4 inches from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, and 10 milliroentgens per hour at one meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded ("off") position.

(b) *Locking of sources of radiation.* Each source of radiation shall be provided with a lock or outer–locked container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer's assistant, or anyone otherwise authorized pursuant to sub. (9) (a). Each storage container shall also be provided with a lock and kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's assistant.

(c) *Storage precautions.* Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

(d) *Radiation survey instruments.* The person in control shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this section and s. HSS 157.12. Each radiation survey instrument shall be calibrated at intervals not to exceed 6 months and after each instrument servicing and a record maintained of the latest date of calibration. Required instrumentation shall have a range such that 2 milliroentgens per hour through one roentgen per hour can be measured.

(9) PERSONAL RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHERS AND RADIOGRAPHER'S ASSISTANTS. (a) *Limitations.* 1. No person in control shall permit any individual to act as a radiographer, as defined in this section, until such individual:

a. Has been instructed in the subjects outlined in Appendix F and shall have demonstrated understanding thereof;

b. Has received copies of and instruction in the rules contained in this section and the applicable subsections of ss. HSS 157.12 and 157.19, including a copy of the registration certificate and the person in control's operating and emergency procedures, and shall have demonstrated understanding thereof; and

c. Has demonstrated competence to use the source of radiation, related handling tools, and survey instruments which will be employed in the radiographer's assignment.

2. No person in control shall permit any individual to act as a radiographer's assistant until such individual:

a. Has received copies of and instruction in the person in control's operating and emergency procedures, and shall have demonstrated understanding thereof; and

b. Has demonstrated competence to use under the personal supervision of the radiographer the sources of radiation, related handling tools, and radiation survey instruments which will be employed in the radiographer assistant's assignment.

(b) *Personnel monitoring control.* No person in control shall permit any individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each such individual shall wear a film or TLD badge and either a pocket dosimeter or pocket chamber. Pocket dosimeters and pocket chambers shall be capable of measuring doses from zero to at least 200 milliroentgens. A film badge shall be assigned to and worn by only one individual.

(10) PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS. (a) *Security.* During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in s. HSS 157.02 (59), except:

1. Where the high radiation area is equipped with a control device or alarm system described in s. HSS 157.12 (3) (d) 2. a. and b., or;

2. Where the high radiation area is locked to protect against unauthorized or accidental entry.

(b) *Posting.* Notwithstanding any provisions in s. HSS 157.12 (3) (d), areas in which radiography is being performed shall be conspicuously posted as required by s. HSS 157.12 (3) (c).

(c) *Radiation surveys and survey records.* No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation as described in sub. (8) (d) is available and used at each site where radiographic exposures are made.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82; correction in (10) (c) made under s. 13.93 (2m) (b) 7., Stats., Register, October, 1991, No. 430**; corrections in (10) made under s. 13.93 (2m) (b) 7., Stats., Register, March, 1996, No. 483**.

HSS 157.16 Radioactivity in community water systems.

(1) APPLICABILITY. (a) *Covered systems.* The provisions of this section establish radioactivity requirements which apply to all community water systems, except those which meet all of the conditions of par. (b).

(b) *Exempt systems.* Community water systems not required to meet the provisions of this section:

1. Consist solely of distribution and storage facilities, without any collection and treatment facilities;

2. Obtain all water from, but are not owned or operated by, a public water system to which the rules of this section apply;

3. Do not sell water to any person; and

4. Are not carriers which convey passengers in interstate commerce.

(2) MAXIMUM CONTAMINANT LEVELS. (a) *Alpha activity.* 1. The maximum containment level for radium–226 and radium–228 in community water systems is 5 pCi/1.

2. The maximum containment level for gross alpha particle activity (including radium–226 but excluding radon and uranium) in community water systems is 15 pCi/1.

(b) *Beta particle and photon radioactivity from man–made radionuclides in community water systems.* 1. The average annual concentration of beta particle and photon radioactivity from man–made radionuclides in drinking water shall not produce an annual dose equivalent to the total body or any internal organ greater than 4 millirem/year.

2. Except for the radionuclides listed in Table A [157–D], the concentration of man–made radionuclides causing 4 mrem total body or organ dose equivalents shall be calculated on the basis of a 2–liter per day drinking water intake using the 168–hour data listed in "Maximum Permissible Body Burdens and Maximum Permissible Concentration of Radionuclides in Air or Water for Occupational Exposure," National Bureau of Standards Handbook 69, as amended August 1963, U.S. department of commerce. (See Appendix G.) If 2 or more radionuclides are present, the sum of their annual dose equivalent to the total body or to any organ shall not exceed 4 mrem/year.

Table 157–D

AVERAGE ANNUAL CONCENTRATIONS ASSUMED TO PRODUCE A TOTAL BODY OR ORGAN DOSE OF 4mREM/YEAR

Radionuclide	Critical Organ	pCi per liter
Tritium	Total body	20,000
Strontium–90	Bone marrow	8

(3) ANALYTICAL METHODS FOR RADIOACTIVITY IN WATER. (a) *Standard radionuclide.* The methods specified in Interim Radiochemical Methodology for Drinking Water, Environmental Monitoring and Support Laboratory, EPA–600/4–75–008 (See Appendix G), or those listed in this paragraph, shall be used to determine compliance with sub. (2) except in cases where alternative methods have been approved in accordance with sub. (5). The following methods are to be used for measuring:

1. Gross Alpha and Beta — Method 703, "Gross Alpha and Gross Beta Radioactivity, Standard Methods for the Examination of Water and Wastewater," 15th edition, American Public Health Association. (See Appendix G.)

2. Total Radium — Method 705, "Radium in Water by Precipitation," ibid

3. Radium–226 — Method 706, "Radium–226 by Radon in Water," ibid.

4. Strontium–89, 90 — Method 704, "Total Strontium and Strontium–90 in Water," ibid.

5. Tritium — Method 708, "Tritium in Water," ibid.

6. Cesium–134 — ASTM D–2459, "Gamma Spectrometry in Water," 1975 Annual Book of ASTM Standards, Water and Atmospheric Analysis, Part 31, American Society for Testing and Materials. (See Appendix G.)

7. Uranium — ASTM D–2907, "Microquantities of Uranium in Water by Fluorometry," ibid.

(b) *Other radionuclides.* When the identification and measurement of radionuclides other than those listed in par. (a) is required, the following references are to be used, except in cases where alternative methods have been approved in accordance with sub. (5):

1. Procedures for Radiochemical Analysis of Nuclear Reactor Aqueous Solutions, H. L. Krieger and S. Gold, EPA–R4–73–014, May 1973. (See Appendix G.)

2. Health and Safety Laboratory Procedure Manual, ERDA–HASL 300, edited by John H. Harley, 1973. (See Appendix G.)

(c) *Sensitivity.* For the purpose of monitoring radioactivity concentrations in drinking water, the required sensitivity of the radioanalysis is defined in terms of a detection limit. The detection limit shall be that concentration which can be counted with a precision of plus or minus 100% at the 95% confidence level (1.96 where is the standard deviation of the net counting rate of the sample).

1. To determine compliance with sub. (2) (a) 1., the detection limit shall not exceed pCi/1. To determine compliance with sub. (2) (a) 2., the detection limits shall not exceed 3 pCi/1.

2. To determine compliance with sub. (2) (b), the detection limits shall not exceed the concentrations listed in Table 157–E.

Table 157–E

DETECTION LIMITS FOR MAN–MADE BETA PARTICLE AND PHOTON EMITTERS

Radionuclide	Detection Limit
Tritium	1,000 pCi/1
Strontium–89	10 pCi/1
Strontium–90	2 pCi/1
Iodine–131	1 pCi/1
Cesium–134	10 pCi/1

Gross beta	4 pCi/1
Other radionuclides	1/10 of the applicable limit

(d) *Compliance.* To judge compliance with the maximum contaminant levels listed in sub. (2), averages of data shall be used and shall be rounded to the same number of significant figures as the maximum contaminant level for the substance in question.

(e) *Availability of publications.* The publications referred to in this subsection are available for inspection at the department, the secretary of state's office and the office of the revisor of statutes.

(4) MONITORING FREQUENCY IN COMMUNITY WATER SYSTEMS. (a) *Monitoring requirements for gross alpha particle activity, radium−226 and radium−228.* 1. Compliance with sub. (2) (a) shall be based on the analysis of an annual composite of 4 consecutive quarterly samples or the average of the analyses of 4 samples obtained at quarterly intervals.

a. A gross alpha particle activity measurement may be substituted for the required radium−226 and radium−228 analyses provided that the measured gross alpha particle activity does not exceed 5 pCi/1 at a confidence level of 95% (1.96 where is the standard deviation of the net counting rate of the sample). In localities where radium−228 may be present in drinking water, the department may require radium−226 and/or radium−228 analyses when the gross alpha particle activity exceeds 2 pCi/1.

b. When the gross alpha particle activity exceeds 5 pCi/1, the same or an equivalent sample shall be analyzed for radium−226. If the concentration of radium−226 exceeds 3 pCi/1, the same or an equivalent sample shall be analyzed for radium−228.

2. For the initial analysis required by subd. 1., data acquired after June 24, 1976 may be substituted at the discretion of the department.

3. Suppliers of water shall monitor water supplies at least once every 4 years following the procedure required by subd. 1. At the discretion of the department, when an annual record taken in conformance with subd. 1. has established that the average annual concentration is less than half the maximum contaminant levels established by sub. (2) (a), analysis of a single sample may be substituted for the quarterly sampling procedure required by subd. 1.

a. More frequent monitoring shall be conducted when ordered by the department in the vicinity of mining or other operations which may contribute alpha particle radioactivity to either surface or groundwater sources of drinking water.

b. A supplier of water shall monitor in conformance with subd. 1 within one year of the introduction of a new water source for a community water system. More frequent monitoring shall be conducted when ordered by the department in the event of possible contamination or when changes in the distribution system or treatment processing occur which may increase the concentration of radioactivity in finished water.

c. A community water system using 2 or more sources having different concentrations of radioactivity shall monitor source water, in addition to water from a free−flowing tap, when required by the department.

d. Monitoring for compliance with sub. (2) (a) after the initial period need not include radium−228 except when required by the department, provided that the average annual concentration of radium−228 has been assayed at least once using the quarterly sampling procedure required by subd. 1.

e. Suppliers of water shall conduct annual monitoring of any community water system in which the radium−226 concentration exceeds 3 pCi/1, when required by the department.

4. If the average annual maximum contaminant level for gross alpha particle activity or total radium as set forth in sub. (2) (a) is exceeded, the supplier of a community water system shall give notice to the department pursuant to sub. (8) and notify the public as required by sub. (9). Monitoring at quarterly intervals shall be continued until the annual average concentration no longer exceeds the maximum contaminant level or until a monitoring schedule as a condition to a variance, exemption or enforcement action shall become effective.

(b) *Monitoring requirements for man−made radioactivity in community water systems.* 1. Systems using surface water sources and serving more than 100,000 persons and such other community water systems as are designated by the department shall be monitored for compliance with sub. (2) (b) by analysis of a composite of 4 consecutive quarterly samples or analysis of 4 quarterly samples. Compliance with sub. (2) (b) may be assumed without further analysis if the average annual concentration of gross beta particle activity is less than 50 pCi/1 and if the average annual concentrations of tritium and strontium−90 are less than those listed in Table A [157−D], provided that if both radionuclides are present the sum of their annual dose equivalents to bone marrow shall not exceed 4 millirem/year.

a. If the gross beta particle activity exceeds 50 pCi/1, an analysis of the sample must be performed to identify the major radioactive constituents present and the appropriate organ and total body doses shall be calculated to determine compliance with sub. (2) (b).

b. Suppliers of water shall conduct additional monitoring, as required by the department, to determine the concentration of man−made radioactivity in principal watersheds designated by the department.

c. At the discretion of the department suppliers of water utilizing only groundwaters may be required to monitor for man−made radioactivity.

2. For the initial analysis required by subd. 1., data acquired since June 24, 1976 may be substituted at the discretion of the department.

3. After the initial analysis required by subd. 1., suppliers of water shall monitor at least every 4 years following the procedure given in subd. 1.

4. The supplier of any community water system designated by the department as utilizing water subject to contamination by effluents from nuclear facilities shall initiate quarterly monitoring for gross beta particle and iodine−131 radioactivity and annual monitoring for strontium−90 and tritium.

a. Quarterly monitoring for gross beta particle activity shall be based on the analysis of monthly samples or the analysis of a composite of 3 monthly samples. The former is recommended. If the gross beta particle activity exceeds 50 pCi/1, an analysis of the sample must be performed to identify the major radioactive constituents present and the appropriate organ and total body doses shall be calculated to determine compliance with sub. (2) (b).

b. For iodine−131, a composite of 5 consecutive daily samples shall be analyzed once each quarter. As required by the department, more frequent monitoring shall be conducted when iodine−131 is identified in the finished water.

c. Annual monitoring for strontium−90 and tritium shall be conducted by means of the analysis of a composite of 4 consecutive quarterly samples or analysis of 4 quarterly samples. The latter procedure is recommended.

d. Data obtained by the direct monitoring of water supplies in the areas surrounding nuclear facilities may be utilized by the supplier where the department determines such data is applicable to a particular community water system.

5. If the average annual maximum contaminant level for man−made radioactivity set forth in sub. (2) (b) is exceeded, the operator of a community water system shall give notice to the department pursuant to sub. (8) and to the public as required by sub. (9). Monitoring at monthly intervals shall be continued until the concentration no longer exceeds the maximum contaminant level or until a monitoring schedule as a condition to a variance, exemption or enforcement action becomes effective.

(5) ALTERNATIVE ANALYTICAL TECHNIQUES. With the written permission of the department concurred in by the administrator of the U.S. environmental protection agency, an alternative analytical technique may be employed. An alternative technique shall be acceptable only if it is substantially equivalent to the prescribed test in both precision and accuracy as it relates to the determination of compliance with any maximum contaminant level. The use of the alternative analytical technique shall not decrease the frequency of monitoring required by sub. (4).

(6) APPROVED LABORATORIES. For the purpose of determining compliance with this section, samples may be considered only if they have been analyzed by a laboratory approved by the department.

(7) MONITORING OF CONSECUTIVE PUBLIC WATER SYSTEMS. When a public water system supplies water to one or more other public water systems, the department of natural resources may modify the monitoring requirements imposed by this section to the extent that the interconnection of the systems justifies treating them as a single system for monitoring purposes. Any modified monitoring shall be conducted pursuant to a schedule specified by the department of natural resources and concurred in by the administrator of the U.S. environmental protection agency.

(8) REPORTING REQUIREMENTS. (a) *Routine reports.* Except where a shorter reporting period is specified in this section, the supplier of water shall report to the department within 40 days following a test, measurement or analysis required to be made by this section, the results of that test, measurement or analysis.

(b) *Noncompliance reporting.* The supplier of water shall report to the department within 48 hours noncompliance with any drinking water rule set forth in this section, including failure to comply with monitoring requirements.

(c) *Exceptions.* The supplier of water is not required to report analytical results to the department when the department performs the analysis.

(9) PUBLIC NOTIFICATION. Public notification shall be provided as prescribed in s. NR 809.81, Wis. Adm. Code.

(10) RECORD MAINTENANCE. The supplier of water shall maintain records as prescribed in s. NR 809.82, Wis. Adm. Code.

(11) VARIANCE AND EXEMPTIONS. Variances and exemptions may be granted from any requirement respecting a maximum contaminant level for radioactivity as prescribed in ss. NR 809.90 and 809.91, Wis. Adm. Code.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82; correction in (9) to (11) made under s. 13.93 (2m) (b) 7., Stats., Register, August, 1995, No. 476.

HSS 157.17 Registration of radioactive materials. **(1)** REQUIREMENT. Radioactive materials produced in an accelerator and naturally occurring radioactive materials must be registered with the department annually, unless exempted under sub. (2) or (3). Application for registration of radioactive material shall be made within 30 days following the effective date of these rules or thereafter prior to the shipment of radioactive materials to the facility. Application for registration shall be completed on forms furnished by the department and shall contain all the information required by the form and accompanying instructions.

(2) EXEMPTION BECAUSE REGULATED BY NRC. Radioactive materials subject to regulation by the U.S. nuclear regulatory commission are exempt from these rules.

(3) EXEMPTION BECAUSE NOT CONSTITUTING UNDUE HAZARD. Small quantities of accelerator–produced materials or naturally occurring radioactive material shall be exempt from registration when the department finds that they do not constitute an undue radiation hazard as determined by standards established by the National Council on Radiation Protection and Measurements or any comparable nationally recognized agency established for the purpose of recommending standards for radiation protection.

Note: See Appendix E for list of exempt quantities.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82.

HSS 157.18 Intrastate transportation of radioactive materials. This section applies to transportation of radioactive material, or delivery of radioactive material to a carrier which is not subject to the rules and regulations of the U.S. department of transportation or other agencies of the United States having jurisdiction over transportation of radioactive materials.

(1) APPLICABLE REQUIREMENTS. No person may transport any radioactive material outside the confines of his or her plant or other authorized location of use, or deliver radioactive material to a carrier for transportation unless the applicable requirements for the mode of transport of the U.S. department of transportation in 49 CFR 170 to 189, 14 CFR 103, and 46 CFR 146, and the U.S. Postal Service in 19 CFR 14 to 15 are met insofar as such regulations relate to the packaging of radioactive material, marking and labeling of packages, loading and storage of packages, placarding of the transporting vehicle, monitoring requirements and accident reporting.

(2) OPERATING PROCEDURES. No person may transport any radioactive material outside the confines of his or her plant or other authorized location of use, or deliver radioactive material to a carrier for transportation unless the person in control has established procedures to safely open and close packages in which radioactive material above exempt quantities is transported and to assure that, prior to delivery to a carrier for transport, each package is property closed for transportation.

(3) SPECIAL OPENING INSTRUCTIONS. No person may transport any radioactive material outside the confines of his or her plant or other authorized location of use, or deliver radioactive material to a carrier for transportation unless prior to delivery of a package to a carrier for transport, the person in control is assured that any special instructions needed to safely open the package are sent to, or have been made available to, the consignee.

History: Cr. Register, September, 1982, No. 321, eff. 10–1–82.

HSS 157.19 Notices, instructions and reports to workers. **(1)** PURPOSE AND SCOPE. This section establishes requirements for notices, instructions and reports by registrants to persons engaged in work for the person in control and the options available to such workers in connection with department inspections to ascertain compliance with the provisions of this chapter and orders issued under it regarding radiological working conditions. This section applies to all persons who receive, possess, use, own or transfer material registered with the department.

(2) POSTING OF NOTICE TO WORKERS. (a) *Documents required.* Each person in control shall post current copies of the following documents:

1. This section and s. HSS 157.12;

2. The certificate of registration, conditions or documents incorporated into the registration by reference and amendments thereto;

3. The operating procedures applicable to work at the installation;

4. Any notice of violation involving radiological working conditions or order issued by the department and any response from the registrant.

(b) *Documents difficult to post.* If posting of a document specified in par. (a) 1., 2., or 3., is not practicable, the person in control may post a notice which describes the document and states where it may be examined.

(c) *Location of documents.* Documents, notices or forms posted pursuant to this subsection shall appear in a sufficient number of places to permit individuals engaged in work under the registration to observe them on the way to or from any particular work location to which the document applies. The documents, notices or forms shall be posted in conspicuous locations, and shall be replaced if defaced or altered.

(d) *Posting time.* Department documents posted pursuant to par. (a) 4., shall be posted within 2 working days after receipt of

the documents from the department. The person in control's response, if any, shall be posted within 2 working days after dispatch from the person in control. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

(3) INSTRUCTIONS TO WORKERS. All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer or use of radioactive material or of radiation in such portions of the restricted area; shall be instructed in the health protection problems associated with exposure to such radioactive material or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable rules of this chapter for the protection of personnel from exposures to radiation or radioactive material occurring in such areas; shall be instructed of their responsibility to report promptly to the person in control any condition which may lead to or cause a violation of the rules of this chapter or unnecessary exposure to radiation or radioactive material; shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and shall be advised as to the radiation exposure reports which workers may request pursuant to sub. (4). The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

(4) NOTIFICATIONS AND REPORTS TO INDIVIDUALS. (a) *Radiation exposure data.* Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual by the person in control as specified in this subsection. The information reported shall include data and results obtained pursuant to the rules, orders, or license conditions, as shown in records maintained by the person in control pursuant to department rules. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the person in control, the name of the individual, and the individual's social security number; include the individual's exposure information; and contain the following statement: "This report is furnished to you under the provisions of Wisconsin Administrative Code Section HSS 157.19. You should preserve this report for further reference."

(b) *Annual notification.* At the request of any worker, each person in control shall advise such worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the person in control pursuant to s. HSS 157.12 (5) (a) 1. and 3.

(c) *Notification to former workers.* At the request of a worker formerly engaged in work controlled by the person in control, each person in control shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the person in control, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive material licensed by or radiation machines registered with the department; and shall include the dates and locations of work under the registration in which the worker participated during this period.

(d) *Notification to over−exposed individuals.* When a person in control is required pursuant to s. HSS 157.12 (5) (d), to report to the department any exposure of an individual to radiation or radioactive material, the person in control shall also provide the individual a report on his [or her] exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the department.

History: Cr. Register, September, 1982, No. 321, eff. 10−1−82.

Next page is numbered 339